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

Islamabad, the 16th November, 2026.

NOTIFICATION

S.R.O. 2118(I)/2026.– 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, 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)
Division of Health and OTC Products (non-drugs)			
1.	Site verification and layout	Site inspection and verification	10,000
2.		Lay out plan per section	10,000
3.		Revision of extension of lay out plan (per section)	10,000
4.	Grant of license	Manufacture for experimental purpose	20,000
5.		Manufacture of bulk extract, homoeopathic tinctures or isolates	60,000
6.		Manufacture by way of formulation	200,000
7.		Import finished product	200,000
8.	Renewal of license	Manufacture for experimental purpose	10,000
9.		Manufacture bulk extract, homoeopathic tinctures or isolates	30,000
10.		Manufacture by way of formulation	100,000
11.		Import finished product	100,000
12.		Renewal of license (within one year after due date)	Applicable renewal fee plus one renewal fee per month
13.	Product registration	Bulk extract, mother tincture or isolate (per product)	10,000
14.		Health product (local manufacture)	20,000
15.		Health product (import)	40,000

Sr.	Regulatory function	Description	Fee (Rs.)
16.		Alternative medicine (local manufacture)	10,000
17.		Alternative medicine (import)	20,000
18.		Homeopathic medicine (local manufacture)	10,000
19.		Homeopathic medicine (import)	20,000
20.		Health product / alternative medicine / homoeopathic medicine (for export purpose)	10,000
21.	Renewal of registration	Health product (local manufacture)	10,000
22.		Health product (import)	20,000
23.		Alternative medicine (local manufacture)	5,000
24.		Alternative medicine (import)	10,000
25.		Homeopathic medicine (local manufacture)	5,000
26.		Homeopathic medicine (import)	10,000
27.		Health product / alternative medicine / homoeopathic medicine (for export purpose)	5,000
28.	Grant / extension / renewal of contract manufacturing permission	For local manufacture health product / alternative medicine / homeopathic product (Form-31)	50,000
29.		For export purpose health product / alternative medicine / homeopathic product (Form-31)	25,000
30.	Duplicate copy	License	10,000
31.		Registration certificate (per document)	10,000
32.	Post license variation	Change of management / company / firm name / title	30,000
33.		Approval of qualified / technical person	10,000
34.	Pre-registration variation	Variance to pre-registration application	10,000
35.	Post registration variation	Correction / standardization of composition of registered product	10,000
36.		Change of principle manufacturer abroad for registered product	20,000
37.		Change of brand name	10,000
38.		Shelf-life extension of registered generic product	10,000
39.		Shelf-life extension of registered new product	10,000
40.		Grant of additional pack (per pack size)	10,000
41.		Change of title / name of market authorization holder (per product)	20,000
42.		Change of registration status from one manufacturer / marketing authorization	20,000
43.			

Sr.	Regulatory function	Description	Fee (Rs.)
		holder to another manufacturer / marketing authorization holder	
44.		Any Post Registration Variation in registered product other than specified	10,000
45.	Attestation of license	--	10,000
46.	Miscellaneous	Any other application having commercial significance	10,000

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

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