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PART II

Statutory Notifications (S.R.O.)

GOVERNMENT OF PAKISTAN

MINISTRY OF NATIONAL HEALTH SERVICES,
REGULATION AND COORDINATION
(Drug Regulatory Authority of Pakistan)

NOTIFICATION

Islamabad, the 16th December, 2022

S. R. O. 2278(I)/2022.—In exercise of the powers conferred by section 23 of the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012), read with sub-section (1) of section 20 thereof, the Drug Regulatory Authority of Pakistan, with the approval of the Federal Government, is pleased to make the following rules, namely:—

CHAPTER-I
PRELIMINARY

1. **Short title, commencement.**—(1) These Rules may be called the Drug Regulatory Authority of Pakistan (Fee and Levy) Rules, 2022.

(5341)

Price: Rs. 6.00

[14006(2022)/Ex. Gaz.]

(2) They shall come into force at once.

2. **Definition.**—(1) In this rules, unless there is anything repugnant in the subject or context,—

(a) “Act” means the Drug Regulatory Authority of Pakistan Act, 2012; and

(b) “Act” means fee as notified by the Authority with the approval of Policy Board.

(2) Word and expressions used but not difined in these Rules shall have the same meaning as assigned thereto in the Act or Rules made thereunder.

CHAPTER-II

LEAVY OF FEE

3. **Levy of fee.**—(1) The Authority shall levy such charges or collect such fees for performance of various functions by it at such rates as is notified by the Authority, from time to time, with the approval of the Policy Board.

(2) The Authority while recommending a fee for any function may take into consideration the factors like cost recovery to meet its expenditures, rupee devaluation etc. as may be considered necessary from time to time.

(3) The Authority shall recommend the fee to the Policy Board for its approval under clause (d) of sub-section (1) of section 11 of the Act.

4. **Determination by the Policy Board.**—(1) The Policy Board shall determine all fees and levies on the recommendations of the Authority for various regulatory funtions.

(2) The Policy Board may also give approval of revision of any fees recommended by the Authority under these rules.

(3) Any fees or its revision after approval of Policy Board shall be notified by the Authority in the official Gazette.

CHAPTER-III

REVISION OF FEE

5. **Fee revision.**—(1) The Authority may annually review the existing fee structure in order to meet its expenditure for functions rendered by it in the light of cost recovery, devaluation of Rupee and consumer price index (CPI).

(2) The Authority for revision of any fee structure shall recommend the increase in fee, if any, for the approval of the Policy Board.

(3) The Policy Board may determine the case of fee increase as recommended by the Authority.

(4) After approval of the Policy Board, the Authority shall notify the increase in the official Gazette.

[No. F. 13-2/2022-DD (LA).]

AAMAR LATIF,
Additional Director (Legal Affairs).