DRUG REGULATORY AUTHORITY
OF PAKISTAN

# Drugs (Appellate Board) Rules, 1976

# DRUGS
# (APPELLATE BOARD) RULES,
# 1976

**S. R. O. 595 (1)/76, dated 2lst June, 1976:** In exercise of the powers conferred by Section 43 of the Drugs Act, 1976 (XXXI of 1976), the Federal Government is pleased to make the following rules, the same having been previously published as required by sub-section (3) of the said section, namely :--

**1. Short title and commencements:**

(1) These rules may be called the Drugs (Appellate Board) Rules, 1976.

(2) They shall come into force at once.

[1][**1A. Conflict of interest. -** A member of the Appellate Board or his representative shall not participate in the proceedings or express any opinion in cases in which conflict of interest arises in respect of matters, dealt with by such member or representative, specified in clause (a) of sub-section (5) of section 11 of the Drugs Act , 1976 (XXXI of 1976).]

**2. The Appellate Board:** [2]{(1) The Appellate Board shall consist of the following members, namely:--

[3][(a) Chief Executive Officer of the Drug Regulatory Authority of Pakistan, who shall be its *ex-officio* Chairman;]

(b) Director Legal Affairs, Drug Regulatory Authority of Pakistan, who shall be its *ex-officio* Secretary;

(c) Secretaries, Departments of Health of the Governments of Punjab, Sindh, Khyber Pakhtunkhwa, Balochistan and Gilgit Baltistan or their nominees not below the rank of an officer in BPS-20, who are experts in medicine, pharmacology or pharmacy and a representative from Federally Administered Tribal Areas, who shall be *ex-officio* members;

(d) one professor of medicine or surgery, to be nominated by the Authority;

(e) one expert in pharmaceutical manufacturing, to be nominated by the Authority;

(f) one professor of pharmacology, to be nominated by the Authority;

(g) one professor of pharmacy, to be nominated by the Authority; and

(h) a co-opted expert in the field related to a specialty case before the Appellate Board, to be nominated by the Chairman of the Appellate Board.}

(2) The members, other than ex-officio members, of the Appellate Board shall hold office for a period of three years and shall be eligible for renominations.

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1. Inserted by S.R.O.664(I)/2005, dated 25-06-2005.
2. Substituted by S.R.O. 475(I)/2013, dated 29-05-2013.
3. Substituted by S.R.O. 674(I)/2015, dated 10-07-2015.

(3) The Appellate Board shall meet as and when required to perform its functions.

(4) The Appellate Board shall have powers to appoint a Committee of Experts for detailed investigation of any matter and report to the Board.

(5) No act or proceeding of the Appellate Board shall be invalid merely on the ground of the existence of any vacancy in, or any defect in the constitution of the Board.

**3. Powers of the Appellate Board:** The [4][ex-officio] members of the Appellate Board shall exercise all the powers of an Inspector without restriction as to area, and such other powers as may be necessary to perform their functions.

**4. Procedure of Appeal:** (1) Any person aggrieved by a decision of the Registration Board, the Central Licensing Board [5][, Pricing Committee] or a licensing authority may, within sixty days of receipt of such decision, submit an appeal to the Appellate Board.

(2) An application for appeal under sub-rule (1) shall be [6][in triplicate and be] accompanied by a copy [7][each of the application which has been rejected] and the decision appealed against, and shall contain all material statements and arguments relied on by the appellant and a fee of [8][fifty] thousand rupees for each application.

[9][(2a) In case of appeal against the decision of the Registration rejecting an application for registration of drug or for fixation of price the application shall be accompanied by a statement in form A or form B of the Schedule to these rules, as the case may be.]

(3) The Appellate Board shall transmit a copy of the application for appeal referred to in sub-rule (2) to the Registration Board or the Central Licensing Board [10][, Pricing Committee] or the licensing authority against whose decision the appeal has been made and such Board or authority shall, on demand, produce before the Appellate Board the record of the case leading to the decision.

(4) The Appellate Board shall, after giving the appellant an opportunity of being heard, pass such orders as it thinks fit and such orders shall be final.

**5. Revision:** The Appellate Board may, of its own motion at any time, call for the record of any case for the purpose of satisfying itself as to the correctness, legality or propriety of such order and may pass such order in relation thereto as it thinks fit.

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4. Inserted by S.R.O. 475(I)/2013, dated 29-05-2013.
5. Substituted by S.R.O. 475(I)/2013, dated 29-05-2013.
6. Words inserted by S.R.O. 12(I)/77, dated 07-06-1978.
7. Substituted by S.R.O. 1453 (I)/78, dated 16-12-1978.
8. Substituted by S.R.O. 463 (I)/2013, dated 29-05-2013.
9. Sub-rule 2(a) inserted by S.R.O 1453(I)/78, dated 16-12-1978**.**
10. Inserted by S.R.O. 475(I)/2013, dated 29-05-2013.

# FORM "A"

*[Under sub-rule( 2a) of Rule 4 of the Drugs (Appellate Board) Rules, 1976]*

1. Name of applicant
2. Name and exact composition of the drug.
3. Name of the manufacturer.
4. Reasons for rejection of the application as communicated by the Registration Board and arguments in support of the appeal.
5. Comparative statement of prices of other competitive and pharmacologically equivalent registered products from different source in support of the economic value of the drug:-

| Name of Product | Name of manufacturer | Price per unit | Estimated cost of full treatment |
|---|---|---|---|
| | | | |

6. Summary of competitive study and advantages of the safety and efficacy with other therapeutically equivalent products.

7. In case of a drug proposed to be manufactured locally, the capacity of the manufacturing section:

| Installed capacity | Utilized capacity | Un-utilized capacity |
|---|---|---|
| | | |

8. Pharmaceutical dosage forms of drugs and total number of drugs in each such form in respect of which registration has been granted to the manufacturer:-

Dosage form …….. Total number of drug ……

Tablets ……

Ampoules ……

Vial ……

Syrup ……..

9. List of drug manufactured in each section etc. in respect of which registration has been granted along with their registration number, strength and pickings.

10. Has at any time any product of the manufacturer been declared substandard. If so please give details of the product and action thereof.

11. Has the manufacturer ever been convicted of violating any of the provisions of the Drug Act 1976, or the rules made thereunder?

12. Have stability studies and, where applicable bioavailability studies, been conducted? If so, please enclose copies of report.

13. Name, qualifications and designations of technical staff responsible for manufacturing and quality control.

14. Has the manufacturer satisfactory facilities for quality control and internal and external specifications for the drug in respect of which appeal is preferred? If so, please give details.

15. Is it a new drug? If so, enclose reports of clinical trial and other material as required by rule 29 of the Drugs (Licensing, Registering and Advertising) Rule 1976.

16. In case of an imported drug, does the appellant posses the following documents from the competent authorities specified at serial No. 20 and 21 of Form 5-A Application form for registration of drugs in Schedule A to the Drugs (Licensing, Registering and Advertising) Rule 1976, namely:-

    a) Certificate of fee sale and G.M.P. and
    b) Certificate of registration with a Photostat copy regarding conditions of registration and labeling in the country of origin.

**INSTRUCTION FOR FILLING THE FORM**

1. The appeal form should be in foolscap.
2. Three copies of the form should be submitted
3. In the statement of comparative study of prices and the statement of comparative study of safety and efficacy, the information in respect of the drug under appeal should be given first and about other products should follow in a tabulated form serial-wise.
4. Serial No. 7 is applicable only in respect of a locally manufactured drug and not to a drug to be imported in finished form.
5. Capacity means the capacity of normal working of a manufacturing section on single-shift basis, and is to be given in terms of total number of units (i.e. tablets, ampoules, vials, bottles with specified sizes) in each section.
6. For the purpose of Serial No.8, the number of drugs will be counted on the basis of number of registrations granted by the Registration Board in case of registered drugs, or the number of items on the basis of the various dosage forms, as the case may be.

*[ inserted vide Notification S.R.O. 1453(I)/78, dated 16th December, 1978]*

# FORM "B"

*[Under sub-rule( 2a) of Rule 4 of the Drugs (Appellate Board) Rules, 1976]*

1. Name of the product .....

   Packing .....

2. Costing statement:

| Cost item | Rate (Invoice enclosed) | Name and address of the exporter | Ingredients of preparation | |
|---|---|---|---|---|
| | | | Quantity | Actual cost as per column |
| 1 | 2 | 3 | 4 | 5 |

(1) Cost of raw material (give details of individual components).
(2) Cost of packing material ((give details of individual components).
(3) Direct labour.
(4) Over-head charges-
   (a) Factory over heads.
   (b) Sales Promotion.
   (c) Miscellaneous.
   (with break up showing minor items).
(5) Profit.
(6) Ex-factory price.
(7) Trade price.
(8) Maximum retail price.

3. Comparative statement of prices of competitive and pharmacologically equivalent products registered from other sources.

| Name of the Product | Source | Price per unit | Estimated cost of full treatment in case of other pharmacologically equivalent product |
|---|---|---|---|
| 1 | 2 | 3 | 4 |

*[ inserted vide Notification S.R.O. 1453(I)/78, dated 16th December, 1978]*