



GUIDELINES FOR REGULATORY APPEALS

Document Number: LEGA/GL/RA/001

Document History: 1st Edition

Effective Date: 15-04-2021

Drug Regulatory Authority of Pakistan
Islamabad - Pakistan



1. HISTORY

This is the first edition of these guidelines.

2. APPLICATION¹-Guideline for Industry

This document is applicable to the industry or any persons aggrieved by any regulatory decision of the Central Licensing Board or the Registration Board or the Licensing Authority or a Board or Authority, to file an appeal against such decision.

3. PURPOSE

These guidelines aim to explain alternate remedy of appeal, against different regulatory decisions, as provided under Section 9 of the Drugs Act 1976 read with Section 7 (u) of the DRAP Act, 2012 and rules made thereunder.

1 The Guidance document is prepared by Drug Regulatory Authority of Pakistan for better illustration of legal requirement, procedures, documentation, and timelines for filing an appeal on a regulatory decision of statutory bodies of DRAP. However, content of guidance document only reflects the current thinking perspective of the Authority on the subject matter. It does not create or confer any rights for or on any person and does not operate to bind Authority or the public.



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4. INTRODUCTION:

The Drugs Act, 1976 ouster the jurisdiction of the court under Section 39, wherein every order passed or decision given by any Board, a Drug Court or any other Authority under the Drugs Act 1976 shall be final and shall not be called in question by or before any court or other authority. Therefore, remedy of appeal is provided under Section 9 of the Drugs Act 1976 read with Section 7 (u) of the DRAP Act, 2012. The Appellate Board determining an appeal will correct errors by any Board or any Committee. The right of appeal ensures that, as far as possible, the Appellate Board arrives at correct decision.

5. LEGAL PROVISIONS:

Appeal is alternate efficacious remedy provided under section 9 of the Drugs Act 1976 read with Section 7 (u) of the DRAP Act, 2012 and rules made there under. The Federal Government has constituted an Appellate Board for the disposal of appeals preferred by person aggrieved by any decision of the Central Licensing Board or the Registration Board or the Licensing Authority or a Board or Authority and for revision of any such decision on its own motion.

6. GENERAL CONSIDERATIONS:

The Honorable Supreme Court of Pakistan in the case of *Kaneez Fatima Vs. Muhammad Salim* reported as **2001 SCMR 1493**, it was held that “By now it is well settled that “where a particular statute provides a self contained machinery for the determination of questions arising under the Act as and where law provides a remedy by appeal or revision to another Tribunal fully competent to give any relief, any indulgence to the contrary by the High Court is bound to produce a sense of distrust in statutory Tribunals. Where, therefore, a petitioner without exhausting his remedy provided by the statute under which he complained had filed a writ petition, it was held that the application in the circumstances would not lie.”



Furthermore, The Hon'ble Supreme Court of Pakistan passed following directions on 03.08.2018 in **Human Rights Case No. 2858 of 2006**:

“5. It is pertinent to mention here that under the law an appellate forum has been provided. Anybody aggrieved of the decision of DRAP in the above matters may challenge the same before the appellate forum. With consensus of all, we direct that instead of approaching the Courts of ordinary jurisdiction i.e., civil courts or High Courts in original jurisdiction or even before agitating the matter in the constitutional jurisdiction of the High Courts, the aggrieved parties shall avail all remedies available to them under the statute.”

The Honorable Supreme Court of Pakistan and the High Courts dismissed number of petitions on the grounds that petitioner did not avail the alternate remedy of appeal provided under the law. Therefore, Applicant is responsible for providing all the necessary information in a timely manner. If the applicant cannot meet this requirement, the decision of any board or committee of the Authority shall get finality under Section 39 of the Drugs Act, 1976.

7. APPELLATE BOARD:

As per the Drugs (Appellate Board) Rules 1976, S.R.O. 674(I)/2015 and other relevant S.R.Os, Appellate Board consists of the following members, namely:--

- (a) Chief Executive Officer of the Drug Regulatory Authority, 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, Baluchistan 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 Area, 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.

8. PROCEDURE FOR APPEAL AGAINST REGULATORY DECISIONS

8.1. Registration Board (RB):

Any person aggrieved by a decision of the Registration Board may, within sixty days of receipt of such decision, submit an appeal to the Appellate Board. Specific requirements to file an appeal vary from case to case. The requirement and procedure for filing an appeal against decision of Registration Board is detailed below;

8.1.1. General Requirements:

- Separate appeal shall be filed for each cause of action.
- An application for interim relief may be filed along with the appeal.
- Prior to the commencement of the meeting of the Board, party may seek deferment on written application which contains the valid reason(s) for deferment, address to the Chairman Appellate Board through Secretary Appellate Board. On the other hand, Appellate Board may decide the matter Ex-party.
- In an appeal only two deferments are allowed.
- In case any deficiency is found in the Appeal filed by aggrieved person. The Secretary Appellate Board shall intimate such deficiency to the Appellant, who shall remove the deficiency within period of 10 days of issuance of deficiency letter. In case the requisite information is not supplied within stipulated time, it would be presumed that appellant is no more interested in the appeal and same shall not be entertained.



8.1.2. Essential Requirements:

- Submission of the appeal in triplicate format on “Form-A” prescribed in Drugs Appellate Board Rules 1976.
- Copy of decision of the Drug Registration Board against which the appeal is to be filed.
- Original Challan form of Rs.50000/= as prescribed fee for appeal duly verified by Statistical Treasury Officer (R&D).
- Affidavit stating that matter contained in the appeal(s) is neither pending for decision before Drug Registration Board nor even before any court of law.
- An affidavit giving sufficient cause for not preferring the appeal(s) within the prescribed period of 60 days as it is time barred.
- Soft copy of the appeal in M/s Word form. (In USB).

8.1.3. Additional Requirements:

- All material statements and arguments relied on.
- Evidence if any.
 - Copy of registration Letter (in case of appeal is made for already registered drug).
 - Registration validity/status (in case of appeal is made for already registered drug).
 - Reasons for rejection of Application by the Drug Registration Board (in case of new application).
 - In case of a drug proposed to be manufactured locally, the capacity of the manufacturing section.
 - Summary of comparative study of advantages of the safety and efficacy of the drug with other therapeutically equivalent products (where required).
 - Stability study data (where required).
 - Copies of reports of bioavailability studies where applied.
 - Details in case any product of appellant has ever been found substandard.
 - Details in case the appellant had ever been convicted of violating any provision of the DRAP Act, 2012, the Drugs Act, 1976 or the rules made there under.
 - Name, qualifications, experience and designation of technical staff responsible for manufacturing and quality control.
 - In case of a new drug, reports of clinical details and other material, as required by rule 29 of the Drug (Licensing, Registering and Advertising) Rules, 1976.



- In case of an imported drugs, the documents from authorities specified at serial No. 20 and 21 of Form – 5 (application form for registration of drugs) in schedule A of the Drugs (Licensing, Registering and Advertising) Rules, 1976.
- Any other information as the Board may require.

8.2. Central Licensing Board (CLB):

Any person aggrieved by a decision of the Central Licensing Board may, within sixty days of receipt of such decision, submit an appeal to the Appellate Board. Specific requirements to file an appeal vary from case to case. The requirement and procedure for filing an appeal against decision of Central Licensing Board is detailed below;

8.2.1. General Requirements:

- Separate appeal shall be filed for each cause of action.
- An application for interim relief may be filed along with the appeal.
- Prior to the commencement of the meeting of the Board, party may seek deferment on written application which contains the valid reason(s) for deferment, address to the Chairman Appellate Board through Secretary Appellate Board. On the other hand, Appellate Board may decide the matter Ex-party.
- In an appeal only two deferments are allowed.
- In case any deficiency is found in the Appeal filed by aggrieved person. The Secretary Appellate Board shall intimate such deficiency to the Appellant, who shall remove the deficiency within period of 10 days of issuance of deficiency letter. In case the requisite information is not supplied within stipulated time, it would be presumed that appellant is no more interested in the appeal and same shall not be entertained.

8.2.2. Essential Requirements:

- Submission of the appeal in triplicate format on “Form-A” prescribed in Drugs Appellate Board Rules 1976.
- Original Challan form of Rs.50000/= as prescribed fee for appeal duly verified by STO (R&D).
- Affidavit stating that matter contained in the appeal(s) is neither pending for decision before Central Licensing Board nor even before any court of law.



- An affidavit giving sufficient cause for not preferring the appeal(s) within the prescribed period of 60 days, in case application is time barred.
- Copy of decision of the Central Licensing Board appealed against.
- Soft copy of the appeal in M/s Word form. (In USB).

8.2.3. Additional Requirements:

- All material statements and arguments relied on.
- Evidence if any.
 - Copy of Drug Manufacturing License (Where applicable).
 - Manufacturing License Validity/status.
 - Reasons for rejection of Application by the Central Licensing Board.
 - Details in case any product of appellant has ever been found substandard.
 - Details in case the appellant had ever been convicted of violating any provision of the DRAP Act, 2012, the Drugs Act, 1976 or the rules made there under.
 - Name, qualifications, experience and designation of technical staff responsible for manufacturing and quality control.
 - Any other information as the Board may require.

8.3. Drug Pricing Committee (DPC):

Any person aggrieved by a decision of the Drug Pricing Committee (DPC) may, within sixty days of receipt of such decision, submit an appeal to the Appellate Board. Specific requirements to file an appeal vary from case to case. The requirement and procedure for filing an appeal against decision of DPC is detailed below;

8.3.1. General Requirements:

- Separate appeal shall be filed for each cause of action.
- An application for interim relief may be filed along with the appeal.
- Prior to the commencement of the meeting of the Board, party may seek deferment on written application which contains the valid reason(s) for deferment, address to the



Chairman Appellate Board through Secretary Appellate Board. On the other hand, Appellate Board may decide the matter Ex-party.

- In an appeal only two deferments are allowed.
- In case any deficiency is found in the Appeal filed by aggrieved person. The Secretary Appellate Board shall intimate such deficiency to the Appellant, who shall remove the deficiency within period of 10 days of issuance of deficiency letter. In case the requisite information is not supplied within stipulated time, it would be presumed that appellant is no more interested in the appeal and same shall not be entertained.

8.3.2. Essential Requirements:

- Submission of the appeal in triplicate format on “Form-B” prescribed in Drugs Appellate Board Rules 1976.
- Original Challan form of Rs.50000/= as prescribed fee for appeal duly verified by STO (R&D).
- Copy of decision of the Drug Pricing Committee appealed against.
- Affidavit stating that matter contained in the appeal(s) is neither pending for decision before Drug Pricing Committee nor even before any court of law.
- An affidavit giving sufficient cause for not preferring the appeal(s) within the prescribed period of 60 days as it is time barred.
- Soft copy of the appeal in M/s Word form. (In USB).

8.3.3. Additional Requirements:

- All material statements and arguments relied on.
- Evidence if any.
 - Reasons for rejection of Application by the Drug Pricing Committee.
 - Details in case any product of appellant has ever been found substandard.
 - Details in case the appellant had ever been convicted of violating any provision of the DRAP Act, 2012, the Drugs Act, 1976 or the rules made there under.
 - Any other information as the Board may require.



8.4. Medical Device Board (MDB):

Any person aggrieved by a decision of the Medical Device Board (MDB) may, within sixty days of receipt of such decision, submit an appeal to the Appellate Board. Specific requirement to file an appeal vary from case to case. The requirement and procedure for filing an appeal against decision of MDB is detailed below;

8.4.1. General Requirements:

- Separate appeal shall be filed for each cause of action. ○ An application for interim relief may be filed along with the appeal.
- Prior to the commencement of the meeting of the Board, party may seek deferment on written application which contains the valid reason(s) for deferment, address to the Chairman Appellate Board through Secretary Appellate Board. On the other hand, Appellate Board may decide the matter Ex-party.
- In an appeal only two deferments are allowed.
- In case any deficiency is found in the Appeal filed by aggrieved person. The Secretary Appellate Board shall intimate such deficiency to the Appellant, who shall remove the deficiency within period of 10 days of issuance of deficiency letter. In case the requisite information is not supplied within stipulated time, it would be presumed that appellant is no more interested in the appeal and same shall not be entertained.

8.4.2. Essential Requirements:

- Submission of the appeal in triplicate format under Rule 60 of the Medical Devices Rules 2017.
- Original Challan form of Rs.50000/= as prescribed fee for appeal duly verified by STO (R&D).
- Affidavit stating that matter contained in the appeal(s) is neither pending for decision before Medical Device Board nor even before any court of law.
- An affidavit giving sufficient cause for not preferring the appeal(s) within the prescribed period of 60 days as it is time barred.
- Copy of decision of the Medical Device Board appealed against.
- Soft copy of the appeal in M/s Word form. (In USB).



8.4.3. Additional Requirements:

- All material statements and arguments relied on.
- Evidence if any.
 - Copy of Establishment License to manufacture/ Copy of Establishment License to import medical devices.
 - Copy of registration/enlistment Letter of class A, B, C, and D medical devices (in case of appeal is made for already registered/enlisted Medical Device).
 - Registration/enlistment validity/status of the class A, B, C and D medical devices (in case of appeal is made for already registered/enlisted Medical Device).
 - Reasons for rejection of Application by the Medical Device Board.
 - Details in case the appellant had ever been convicted of violating any provision of the DRAP Act, 2012, the Drugs Act, 1976 or the rules made there under.
 - Name, qualifications, experience and designation of technical staff responsible for manufacturing and quality control.
 - In case of a new medical device records including adequately organized and index files, as required by rule 19 sub rule 8 of the Medical Devices Rules, 2017 shall be provided.
 - In case of an Import or Export of Medical Device, did the applicant fulfill all the requirements mentioned in rule 21 to 37 of the Medical Devices Rules, 2017.
 - Any other information as the Board may require.

8.5. Enlistment Evaluation Committee (EEC):

Any person aggrieved by a decision of the Enlistment Evaluation Committee (EEC) may, within thirty days of receipt of such decision, submit an appeal to the Appellate Board. Specific requirement to file an appeal vary from case to case. The requirement and procedure for filing an appeal against decision of EEC is detailed below;

8.5.1. General Requirements:

- Separate appeal shall be filed for each cause of action.



- An application for interim relief may be filed along with the appeal.
- Prior to the commencement of the meeting of the Board, party may seek deferment on written application which contains the valid reason(s) for deferment, address to the Chairman Appellate Board through Secretary Appellate Board. On the other hand, Appellate Board may decide the matter Ex-party.
- In an appeal only two deferments are allowed.
- In case any deficiency is found in the Appeal filed by aggrieved person. The Secretary Appellate Board shall intimate such deficiency to the Appellant, who shall remove the deficiency within period of 10 days of issuance of deficiency letter. In case the requisite information is not supplied within stipulated time, it would be presumed that appellant is no more interested in the appeal and same shall not be entertained.

8.5.2. Essential Requirements:

- Submission of the appeal in triplicate format under rule 7 sub rule 15 of the Alternative Medicines and Health Products (Enlistment) Rules 2014.
- Original Challan form of Rs.50000/= as prescribed fee for appeal duly verified by STO (R&D).
- Copy of decision of the Enlistment Evaluation Committee appealed against.
- Affidavit stating that matter contained in the appeal(s) is neither pending for decision before Enlistment Evaluation Committee nor even before any court of law.
- An affidavit giving sufficient cause for not preferring the appeal(s) within the prescribed period of one month as it is time barred.
- Soft copy of the appeal in M/s Word form. (In USB).

8.5.3. Additional Requirements:

- All material statements and arguments relied on.
- Evidence if any.
 - Copy of Provisional Certificate for Establishment as a manufacturer/importer.
 - Copy of Provisional Certificate for enlistment of product(in case of appeal is made for already enlisted product).
 - Reasons for rejection of Application by the Enlistment Evaluation Committee.



- Details in case the appellant had ever been convicted of violating any provision of the DRAP Act, 2012, the Drugs Act, 1976 or the rules made there under.
- Name, qualifications, experience and designation of technical staff responsible for manufacturing and quality control.
- In case of a new medicine Evidence of clinical safety and efficacy based on Pre-clinical and clinical studies along with data, as required by Form-5 of the Alternative Medicines and Health Products (Enlistment) Rules 2014.
- In case of an Import of Alternative Medicines and Health Products, does the applicant possess the documents from the authorities specified at serial no. 9 of Form-5 of the Alternative Medicines and Health Products (Enlistment) Rules 2014.
- Stability study data (where required).
- Any other information as the Board may require.

8.6. Import and Export Section (I&E):

Any person aggrieved by a decision of the Licensing Authority may, within sixty days of receipt of such decision, submit an appeal to the Appellate Board. Specific requirement to file an appeal vary from case to case. The requirement and procedure for filing an appeal against decision of Licensing Authority is detailed below;

8.6.1. General Requirements:

- Separate appeal shall be filed for each cause of action.
- An application for interim relief may be filed along with the appeal.
- Prior to the commencement of the meeting of the Board, party may seek deferment on written application which contains the valid reason(s) for deferment, address to the Chairman Appellate Board through Secretary Appellate Board. On the other hand, Appellate Board may decide the matter Ex-party.
- In an appeal only two deferments are allowed.
- In case any deficiency is found in the Appeal filed by aggrieved person. The Secretary Appellate Board shall intimate such deficiency to the Appellant, who shall remove the deficiency within period of 10 days of issuance of deficiency letter. In case the requisite information is not supplied within stipulated time, it would be presumed that appellant is no more interested in the appeal and same shall not be entertained.



8.6.2. Essential Requirements:

- Submission of the appeal in triplicate format on “Form-A” prescribed in Drugs Appellate Board Rules 1976.
- Original Challan form of Rs.50000/= as prescribed fee for appeal duly verified by STO (R&D).
- Copy of decision of the Licensing Authority appealed against.
- Affidavit stating that matter contained in the appeal(s) is neither pending for decision before Licensing Authority nor even before any court of law.
- An affidavit giving sufficient cause for not preferring the appeal(s) within the prescribed period of 60 days as it is time barred.
- Soft copy of the appeal in M/s Word form. (In USB).

8.6.3. Additional Requirements:

- All material statements and arguments relied on.
- Evidence if any.
 - Copy of License to import/export of drugs (in case the license is already issued by licensing Authority)
 - Drug import/export license Validity/status.
 - Reasons for rejection of Application by the Licensing Authority.
 - Details in case any import/export product of appellant has ever been found substandard.
 - Details in case the appellant had ever been convicted of violating any provision of the DRAP Act, 2012, the Drugs Act, 1976 or the rules made there under.
 - Any other information as the Board may require.



9. WHERE TO APPLY:

All applications shall be sent to following address;

Secretary, Appellate Board,
Legal Affairs Division
Drug Regulatory Authority of Pakistan.
7th Mauve Area, Telecom Foundation
Complex, G9/4, Islamabad.

10. REFERENCE:

- Drug Regulatory Authority of Pakistan Act, 2012
- The Drugs Act, 1976.
- Medical Devices Rules 2017.
- Alternative Medicine & Health Product (Enlistment) Rules 2014.
- The Drug (Licensing Registration & Advertising) Rules, 1976.
- The Drugs (Import & Export) Rules 1976.
- The Drugs (Appellate Board) Rules 1976.

11. FORMS:

- Form-A
- Form-B



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 possess 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 free 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 labor.
- (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]

DRUG REGULATORY AUTHORITY OF PAKISTAN
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