OVERVIEW OF DECISION MAKING BODIES AND COMMUNICATION CHANNELS

"FOR REGULATION OF THERAPEUTIC GOODS IN PAKISTAN"

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Drug Regulatory Authority of Pakistan

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Edition History

Change #	Effective date	Revision date	Reason for Revision
Edition 01	11-10-2021	18-11-2022	-
Edition 02	12-12-2022		The 1st edition of these guidelines was drafted as per draft Pharmacovigilance Rules and had sections that was related to composition and function of PRAEC. As the Pharmacovigilance Rules, 2022 are officially notified, therefore, this 2nd edition of guidelines was redrafted in line with Pharmacovigilance Rules, 2022 and all these sections have been amended.

1. HISTORY

This is the 2nd edition of this document.

2. APPLICATION

This document covers all major decision making bodies of regulatory oversight of therapeutic goods, their scope of working, processes followed along with communication channels between these decision making bodies for effective coordination, information sharing and harmonization.

3. PURPOSE

3.1. Purpose of this document is to elaborate a complete structure of organizational decision making bodies, their processes and communication channels, which are in place for performing various functions as mandated under the DRAP Act, 2012, the Drugs Act, 1976 and rules framed thereunder. This document will provide a comprehensive over view of all decision making bodies, their legal mandate, structure, processes followed and communication channels to carryout purpose of the DRAP Act, 2012 i.e. regulation of therapeutic goods.

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4. INTRODUCTION

4.1. Drug Regulatory Authority of Pakistan was established under the Drug Regulatory Authority of Pakistan Act, 2012. Drug Regulatory Authority of Pakistan (DRAP) is mandated to provide for effective coordination and enforcement of The Drugs Act, 1976 (XXXI of 1976) and to bring harmony in inter-provincial trade and commerce of therapeutic goods. In this regard manufacture, import and export is regulated by the DRAP. While sale, storage, and distribution is the mandate of provincial governments. Each provincial government has its own set of rules to run affairs under their mandate. While in provincial capital, sale, storage and distribution of therapeutic goods is regulated by the Islamabad Capital Administration. DRAP is responsible for ensuring that therapeutic goods approved and available in market meet prescribed standards of quality, safety and efficacy and are sold at reasonable prices. This includes registration and marketing authorization, vigilance, market surveillance and control, licensing establishments, regulatory inspection, laboratory testing, clinical trials oversight, pharmacovigilance and lot release of biologicals.

4.2. Therapeutic goods regulated by the DRAP include drugs, biological, medical devices, alternative medicines & health products. Previously, scope was limited to Drugs and Biologicals, however, it was extended to other categories after enactment of the Drugs Regulatory Authority of Pakistan Act, 2012.

4.3. Drug Regulatory Authority of Pakistan (DRAP) has been established by the Federal Government. It is placed under the administrative control of Ministry of National Health Services, Regulations & Coordination. General direction, Administration and monitoring of the Authority vests with Policy Board of DRAP. Drug Regulatory Authority of Pakistan (DRAP) is the main constitutional body to regulate therapeutic goods. DRAP has thirteen Divisions, these Division performs the functions as mandated to them under the DRAP Act, 2012. In these Division mandated functions are performed through Boards and Committee, while officers in each Division also has decision making powers for functions assigned or entrusted or delegated to them. Channels are communication between cross cutting functions are well established for coordinated and harmonized activities.

5. DEFINITIONS AND ACRONYMS

5.1	**FG**	Federal Government.
5.2	**PB**	Policy Board.
5.3	**Act**	Drug Regulatory Authority of Pakistan Act, 2012
5.4	**Drugs Act**	Drugs Act, 1976
5.5	**M/o.NHS,R&C**	Ministry of National Health Services, Regulations & Coordination
5.6	**DRAP**	Drug Regulatory Authority of Pakistan

5.7	**PE&R**	Pharmaceutical Evaluation & Registration
5.8	**DLIC**	Drug Licensing
5.9	**MDMC**	Medical Devices & Medicated Cosmetics
5.10	**BD**	Biological Drugs
5.11	**CD**	Controlled Drugs
5.12	**PS**	Pharmacy Services
5.13	**H&OTC**	Health & OTC Products
5.14	**C&P**	Costing & Pricing
5.15	**B&A**	Budget & Accounts
5.16	**A,HR&L**	Admin, Human Resource & Logistics
5.17	**LA**	Legal Affairs
5.18	**MIS**	Management Information System
5.19	**CEO**	Chief Executive Officer
5.20	**AB**	Appellate Board
5.21	**CLB**	Central Licensing Board
5.22	**RB**	Registration Board
5.23	**MDB**	Medical Devices Board
5.24	**EEC**	Enlistment Evaluation Committee
5.25	**DPC**	Drug Pricing Committee
5.26	**CoA**	Committee on Advertisement
5.27	**CSC**	Clinical Study Committee
5.28	**R&D**	Research & Development
5.29	**PRAEC**	Pharmacovigilance Risk Assessment Expert Committee
5.30	**CAQCS**	Committee for Allocation of Quota of Controlled Substances
5.31	**NPC**	National Pharmacovigilance Centre
5.32	**FID/FIDs**	Federal Inspector of Drugs/Federal Inspectors of Drugs
5.33	**DTLs**	Drug Testing Laboratories
5.34	**MRP**	Maximum Retail Price
5.35	**DPP**	Drug Pricing Policy 2018
5.36	**DML**	Drug Manufacturing License
5.37	**GMP**	Good Manufacturing Practice
5.38	**API**	Active Pharmaceutical Ingredient
5.39	**FSC**	Free Sale Certificate
5.40	**CRO**	Contract Research Organization
5.41	**NICB**	National Interventional Cardiology Board
5.42	**LSMDs**	Life Saving Medical Devices
5.43	**BA**	Bio-Availability
5.44	**BE**	Bio-Equivalence
5.45	**IRB**	Institutional Review Board

5.46	**PBRER**	Periodic Benefits-Risk Evaluation Report
5.47	**DSUR**	Development Safety Update Report
5.48	**RMP**	Risk Management Plan
5.49	**PASS**	Post-Authorization Safety Study
5.50	**GVP**	Good Vigilance Practices
5.51	**PG**	Provincial Government
5.52	**PQCB**	Provincial Quality Control Board
5.53	**Drugs (LRA) Rules**	Drugs (Licensing, Registering & Advertising) Rules, 1976
5.54	**Drugs (I&E) Rules**	Drugs (Import & Export) Rules, 1976

6. FEDERAL GOVERNMENT (see section 43 of the Drugs Act, 1976 and 23 of the DRAP Act, 2012)

6.1. FG is consisting of the Prime Minister and the Federal Ministers, which act through the Prime Minister, who shall be the chief executive of the Federation. Under the Act, FG has following roles and responsibilities in the operations of the DRAP:-

6.1.1. Appointment of Chief Executive Officer of DRAP on the recommendations of the Policy Board of DRAP under Section 5(1) and (6) of the DRAP Act, 2012.

6.1.2. Appointment of Directors of the Authority on the recommendations of the Policy Board of DRAP under Section 4 of the DRAP Act, 2012.

6.1.3. Increase or decrease in the 13 established Division of the DRAP, on the basis of recommendations of the Policy Board under Section 4(2) of the DRAP Act, 2012 and to prescribe their functions and the relevant experience, qualification, terms, mode and manner of appointment of Directors and related staff in each Division.

6.1.4. Assign duties and functions to the DRAP for furthering the provision of the Act.

6.1.5. Appoint six Expert Members of PB under Section 9(3) of the Act.

6.1.6. Review the audit report of the Authority under Section 22(5) of the Act.

6.1.7. Make rules for carrying out purpose of the Act, on the recommendations of the DRAP under Section 23 of the Act.

6.1.8. Review annual reports of the DRAP under Section 25 of the Act.

6.1.9. Amendment of any schedule of the Act, on the recommendations of the Policy Board under Section 35 of the Act.

6.1.10. Remove difficulties for effective implementation of the Act under Section 36 of the Act.

6.1.11. Grant approval to the DRAP for cooperation with international organizations under Section 39 of the Act.

6.1.12. Policy directive to the Federal Government under Section 41 of the Act.

6.1.13. Approval of members of various Board and Committee wherein approval under respective rules is required from the Federal Government on the recommendations of the DRAP.

6.1.14. Notification of expert committees under Section 10 of the Drugs Act, 1976

6.1.15. Notification of Committee on advertisement of therapeutic goods under Section 10 of the Drugs Act, 1976 and Section 7(a) of the Act and approval of advertisement.

6.1.16. Approval of prices of drugs and biologicals under Section 12 of the Drugs Act, 1976.

6.1.17. Appoints Federal Government Analyst under Section 16 of the Drugs Act, 1976.

6.1.18. Appoints Federal Inspectors of Drugs (FIDs) under Section 17 of the Drugs Act, 1976 on the recommendations of the Authority.

6.1.19. Establishment of Drug Courts under Section 31 of the Drugs Act for prosecution of contraventions under the Drugs Act, DRAP Act and the rules framed thereunder.

6.1.20. Establishment of Drug Testing Laboratories (DTLs) for testing and research purposes.

6.1.21. Approval of expert members of various boards and committees.

6.1.22. To grant exemption from any of the provisions of the Drugs Act under Section 36 of the Drugs Act.

6.2. Communication channel between DRAP and FG is through M/o.NHS,R&C. Matters related to FG are forwarded through M/o.NHS,R&C in the form of summaries. Decision from Federal Government are received through M/o.NHS,R&C in the form of minutes of meeting of Federal Government. Decisions are communicated in the form of statutory notifications published in the Official Gazette for information of all stakeholders and their implementation.

7. MINISTRY OF NATIONAL HEALTH SERVICES, REGULATION & COORDINATION *(No.4-4/2012-min-I dated 3rd April, 2020)*

7.1. M/o.NHS,R&C has administrative control over DRAP and serves as a bridge between DRAP and Federal Ministries & allied departments on matter related to DRAP. The communication is in the form of movement of official files, letter and U.O notes, etc.

7.2. In developing a strategy on the use of reliance in regulatory functions and activities, DRAP considered possible approaches in the context of the needs and

characteristics of the national health and regulatory system together with the current human resource strengthens, capabilities and proper use of available financial resources. The decision to practice reliance has been taken keeping into consideration the available legal provisions, existing capacities, regulatory systems' needs, increase the quality of regulatory decisions, reduce duplication of effort and, ultimately, promote timely access to safe, efficacious and quality-assured therapeutic goods.

8. POLICY BOARD (see section 9 of the DRAP Act, 2012)

8.1. The general direction, administration and monitoring of the Authority shall vest in the Policy Board constituted under Section 9 of the DRAP Act, 2012 which consists of following members:

S.no	NAME/DESIGNATION	STATUS/SPECIALITY
8.1.1	The Secretary, Ministry of National Health Services, Regulations & Coordination, Chairperson.	Ex-Officio member/ Chairman of the Board.
8.1.2	The Secretary, Health Department, Governments of the Punjab.	Ex-Officio member
8.1.3	The Secretary, Health Department, Governments of the Sindh.	Ex-Officio member
8.1.4	The Secretary, Health Department, Governments of the Khyber Pakhtunkhwa.	Ex-Officio member
8.1.5	The Secretary, Health Department, Governments of the Baluchistan.	Ex-Officio member
8.1.6	The Secretary, Health Department, Governments of the Gilgit Baltistan.	Ex-Officio member
8.1.7	Representative of Ministry of Law & Justice not below BPS-20.	Member/ Law Expert
8.1.8	Six experts from the public and private sector of various specialities.	Technical Member/Drug Regulation & Pharmacy Services
8.1.9	The Chief Executive Officer, Drug Regulatory Authority of Pakistan, Secretary of the Board.	Ex-Officio Member/ Secretary of the Board

8.2. The Board has following functions:

8.2.1. Under Section 11 of the DRAP Act, 2012:

8.2.1.1. Frame the policy and provide guidelines based on global and regional trends to the Authority and monitor the implementation and performance of the guidelines and of the functions of the Authority ensuring good governance and accountability;

8.2.1.2. Monitor and supervise all the functions of the Authority;

8.2.1.3. Approve the Budget of the Authority; and

8.2.1.4. Determine all fees and levies.

8.2.2. To approve regulations for internal working and terms & conditions of employees of Authority on the recommendations of the Authority under Section 24 of the DRAP Act, 2012.

8.2.3. Recommendations to the FG for appointment of Chief Executive Officer of DRAP under Section 5(1) and (6) of the DRAP Act, 2012.

8.2.4. Appointment of Directors of the Authority on the recommendations of the Policy Board of DRAP under Section 4 of the DRAP Act, 2012.

8.2.5. Recommendations to FG for increase or decrease in the 13 established Division of the DRAP under Section 4(2) of the DRAP Act, 2012 and to prescribe their functions and the relevant experience, qualification, terms, mode and manner of appointment of Directors and related staff in each Division.

8.2.6. Recommendations to the FG for amendment of any schedule of the Act under Section 35 of the Act.

8.2.7. Recommend to FG for fixation / increase / decrease of price under Paragraph 12(8) of the Drug Pricing Policy (DPP), 2018.

8.2.8. Regulation of mechanism for fixation of MRP of drugs / biologicals which are not covered under the DPP 2018 under Section 12(4) of the aforesaid policy.

8.3. Communication with the Policy Board is through Secretariat working under CEO, DRAP. CEO is a secretary cum member of the Policy Board. Matter requiring approvals of Policy Board are forwarded to CEO, office for inclusion in the working paper for the Policy Board and the decisions of the DRAP requiring consideration and approval of the Policy Board are also included in the working paper. Working paper is circulated with the approval of the Chairman, Policy Board/Secretary, M/o.NHS,R&C. Decisions are communicated in the form of minutes of the meeting of the Policy Board by CEO, office, DRAP. Decision are implemented in various modes depending upon the type of decision taken by the Policy Board.

9. DRUG AUTHORITY OF PAKISTAN (see section 4 of the DRAP Act, 2012 vide Notification No. 1-1/2012-DRAP/BILL 28th November, 2012)

9.1. Drug Regulatory Authority of Pakistan is consisting of 13 Directors of the Authority and is headed by the CEO, DRAP and is established under Section 4 of the Act. Composition of the Authority is as under:-

S.No.	Designation	Status
9.1.1	Chief Executive Officer	Chairman
9.1.2	Director Costing and Pricing	Member
9.1.3	Director Budget & Accounts	Member
9.1.4	Director Biological Drugs	Member
9.1.5	Director Pharmacy Services	Member
9.1.6	Director (Health & OTC)	Member
9.1.7	Director (Licensing)	Member
9.1.8	Director Quality Assurance & Laboratory Testing.	Member.
9.1.9	Director Medical Devices & Medicated Cosmetics	Member
9.1.10	Director Pharmaceutical Evaluations & Registration	Member
9.1.11	Director Administration, HR & Logistics	Member
9.1.12	Director Management Information Services	Member
9.1.13	Director Controlled Drugs Division	Member
9.1.14	Director Legal Affairs	Member

9.2. The powers and functions of the Authority under Section 7 of the Act are:

9.2.1. Administer the laws specified in the Schedule-VI that apply to Federal Government, and advise the Provincial Governments for the laws that are applicable to the Provinces;

9.2.2. Monitor the enforcement of laws specified in the Schedule-VI and collect relevant data and information;

9.2.3. Issue guidelines and monitor the enforcement of:

9.2.3.1. Licensing of the manufacture of therapeutic goods;

9.2.3.2. Registration of therapeutic goods;
9.2.3.3. Regulation for the advertisement;
9.2.3.4. Drug specifications and laboratory practices;
9.2.3.5. Prosecution and appeals under this Act and the Drugs Act, 1976 (XXXI of 1976) relating to Federal subject;
9.2.3.6. Regulation and allocation of quota of narcotic drugs, psychotropic substances and precursor substances (chemicals) in consultation with Federal Government;
9.2.3.7. Regulation for pricing and mechanism for fixation of prices of various therapeutic goods under its ambit;
9.2.3.8. Determining standards for biological manufacturing and testing;
9.2.3.9. Implementation of internationally recognized standards such as good laboratory practices, current good manufacturing practices, good distribution practices, cold chain management, bioequivalence studies, stability studies, anti-spurious codes, clinical trials, biosimilar evaluations, and endorsement and systematic implementation of World Health Organization, International Conference on Harmonizations and Food and Drug Administration guidelines etc.
9.2.3.10. Regulation, enforcement and monitoring of advertisement rule and ban on false advertisement;
9.2.3.11. Manufacturing of active pharmaceutical ingredients in all its forms; and (xii) use of central research fund.

9.2.4. Coordinate, monitor or engage, in conjunction with other organizations, Provincial. Governments and international agencies, in training, study or project related to therapeutic goods. The Authority may engage any individual or counsel to advise or work for managing national and international opportunities for training, education, seminars, conferences etc., with a view to improve capacity building;

9.2.5. Facilitate advancement and up gradation of the sector to meet international standards and also to promote manufacture and export of active pharmaceutical ingredients and therapeutic goods;

9.2.6. Coordinate at policy level and provide policy guidance to the Provincial Government in the performance of their functions with a purpose to bring uniformity;

9.2.7. Facilitate the procurement and implementation of foreign aided technical assistance on therapeutic goods where such expertise does not exist but its existence would promote public health;

9.2.8. Take steps for development and promotion of pharmacy services;

9.2.9. Undertake awareness campaigns regarding prevention of diseases, patients' rights, healthcare privileges etc., through media, seminars, publications, and other available means of information technology;

9.2.10. Issue guidelines and monitor proceedings and funding and accounts of health seminars, workshops and conferences;

9.2.11. Advise the Federal Government on issues related to obligations and commitments related to therapeutic goods;

9.2.12. Appoint such employees, consultants and experts as deemed necessary on prescribed terms and conditions including their salaries and remunerations with consultation and approval of the Board. Such recruitment, continuation and remuneration shall be based on merit and productivity;

9.2.13. Prescribe rules for seniority, promotion, code of conduct and terms and condition of service of its employees;

9.2.14. Levy such charges or fees as may be prescribed for services and facilities provided by the Authority and its offices;

9.2.15. Enter into contract for the supply of materials or for the execution of works as may be necessary for the discharge of any of its duties and functions;

9.2.16. Prepare annual budget to be approved by the Board;

9.2.17. To monitor and regulate the marketing practices, so as to ensure rational use of drugs, and ethical criteria for promotion of therapeutic goods in line with international practices;

9.2.18. Develop working manuals, guidelines, references, materials and procedures in order to improve the working environment of offices etc., set up under the Authority;

9.2.19. Prescribe, regulate or implement measures and standards on matters related or connected with the Authority;

9.2.20. Develop, issue, adopt, and enforce the standards and guidelines to ensure safety, efficacy, and quality of therapeutic goods with rational use at reasonable price;

9.2.21. Perform licensing, registration, pricing and appellate function thereof;

9.2.22. Coordinate with provincial governments and international agencies for smooth implementation of laws, capacity building and training of the regulatory staff;

9.2.23. Develop standard operating procedures, manuals, guidelines for transparent working of offices and conduct quality audits for conformance of the same;

9.2.24. Establish system of cost recovery to ensure financial autonomy and efficient functioning of the authority without becoming burden on the government; and

9.2.25. Perform and carry out any other act, duty or function as may be assigned to it by the Policy Board and the Federal Government for furthering the provisions of this Act.

9.2.26. Approval of expert members of various boards and committees.

9.2.27. Recommendations to FG for approval of expert members of various boards and committees.

9.3. Functions as assigned to the Authority under Section 4 of the Act, are performed through thirteen Division of the Authority, the detail of the functions performed by each Division is tailored below:-

9.3.1. **Division of Pharmaceutical Evaluations and Registration:**-Division of Pharmaceutical Evaluations and Registration is responsible for the evaluation, assessment and registration of pharmaceuticals drugs for human beings, animals and to perform other functions connected therewith and assigned by the Registration Board;

9.3.2. **Division of Drug Licensing.-** Division of Drug Licensing is responsible for the licensing of the drugs manufacturing facilities and to perform other functions connected therewith;

9.3.3. **Division of Quality Assurance and Laboratory testing.-.** Division of Quality Assurance and Laboratory testing is responsible for enforcement of current Good Manufacturing Practices under the Act, and for testing or research of drugs and to perform other functions connected therewith. The Division also perform the functions related to post marketing surveillance and evaluation, coordination and monitoring of safety, efficacy and quality of registered drugs and inactive materials including the clinical and toxicological study, drug recalls and withdrawls, and to perform other functions connected therewith;

9.3.4. **Division of Medical Devices and Medicated Cosmetics.-** Division of Medical Devices and Medicated Cosmetics is responsible for the assessment, enlistment or registration of medical devices and medicated cosmetics, medicated shampoos and medicated soaps for human beings, animals and ·to perform other functions connected therewith;

9.3.5. **Division of Biological Drugs.-** Division of Biological Evaluation and Research is responsible for the evaluation, assessment, registration and licensing of Biologicals for human beings, animals and to perform other functions connected therewith including all the functions of national control authority for biologicals· as required for the prequalification by World Health Organizations of locally manufactured human biological drugs;

9.3.6. **Division of Controlled Drugs.-** Division of Controlled Drugs in consultation with the Federal Government is responsible for regulation and allocation of quota of narcotic drugs, psychotropic substances and precursor chemicals and to perform other functions connected therewith;

9.3.7. **Division of Pharmacy Services.-** Division of Pharmacy Services is responsible for the development and promotion of pharmacy services and to perform other functions connected therewith; ·

9.3.8. **Division of Health and OTC Products (non-drugs).-** Division of Health and OTC Products (non-drugs) is responsible for the assessment, licensing and registration of Alternative Medicines such as Ayurvedic, Chinese, Unani and Homeopathy, enlistment or registration of nutritional products and food supplements for human beings, animals and to perform other functions connected therewith;

9.3.9. **Division of Costing and Pricing.-** Division of Costing and Pricing is responsible for the costing and pricing of therapeutic goods and to perform other functions connected therewith;

9.3.10. **Division of Budget and Accounts.-** Division for Budget and Accounts is responsible for budgetary and financial aspects of the Authority and other daily accounting matters connected therewith or ancillary thereto;

9.3.11. **Division of Administration, Human Resource and Logistics.-** Division for Administration, Human Resource and Logistics is responsible for administration, recruitment, appointment, capacity building and development for the Authority and other matters connected therewith and ancillary there to;

9.3.12. **Division of Legal Affairs.-** Division for Legal Affairs which is responsible for legal aspects of the Authority and other matters connected with Drug Court and other court cases therewith or ancillary thereto; and

9.3.13. **Division of Management Information Services.-** Division for Management Information Services is responsible for development of automation of .functions using information technology for the Authority and other matters connected therewith and ancillary there to;

9.4. Communication with the Authority is through Secretariat working under CEO, DRAP. Working paper is circulated with the approval of the CEO, DRAP. Decisions are communicated in the form of minutes of the meeting of the Authority by CEO office, DRAP. Decision are implemented in various modes depending upon the type of decision taken by the Authority. Matter requiring approvals of Policy Board are included in the working paper of the Policy Board or forwarded to CEO office for inclusion in the working paper for the Policy Board.

10. Chief Executive Officer (CEO) (see section 5 of the DRAP Act, 2012)

10.1. Chief Executive Officer (CEO) appointed under Section 5 of the Act, 2012 shall:

10.1.1. Exercise general control and supervision over the affairs of the Authority;

10.1.2. Ensure the provisions of the Act, the rules, the regulations, policies and directions of the Board are properly executed;

10.1.3. Discharge such duties and perform such functions as are assigned to him by or under the Act or as may be prescribed by the Board; and also

10.1.4. Act as:

10.1.4.1. Chairman of the Authority.

10.1.4.2. Chairman of the Appellate Board.

10.1.4.3. Secretary cum Member of the Policy Board.

10.1.4.4. Licensing Authority for import & export related activities related to therapeutic goods.

10.2. The CEO has the power to,-

10.2.1. Authorize expenditure provided for in the budget in accordance with the rules and regulations;

10.2.2. Re-appropriation of funds within the approved budget;

10.2.3. Supervision of administrative affairs of the Authority including but not limited to transfer / posting, grant of leave, recruitment, trainings, workshops, seminars etc.

10.2.4. Delegate his powers to appropriate levels of management subject to such conditions as he may deem fit.

10.3. Matter requiring approval / consideration are forwarded to the CEO on files / noting from relevant Division. Decision is also in the form of approvals on file(s) and noting(s). Decision taken by CEO are communicated by the relevant Divisions in the form of notification, letter, sanctions, approval and other modes of official communications as per Secretariat Instructions.

11. STATUTORY BOARDS AND COMMITTEES

11.1. Appellate Board *(see section 9 of the Drugs Act, 1976)*

11.1.1. Appellate Board is constituted under Section 9 of the Drugs Act for the disposal of appeals preferred by persons aggrieved by any decision of the Central Licensing Board or the Registration Board or the Licensing Authority or a Board or Authority to which the powers of the Federal Government under section 12 have been delegated under sub-section (3) of that section and for revision of any such decision on its own motion.

11.1.2. Composition of the Appellate Board is provided under Rules 2 of the Drugs (Appellate Board) Rules, 1976. Composition of the Appellate Board is as under:-

S.No.	Designation	Status
11.1.2.1	Chief Executive Office, Drug Regulatory Authority of Pakistan	Ex-Officio Chairman
11.1.2.2	Director, Legal Affairs, Division, Drug Regulatory Authority of Pakistan	Ex-Officio Secretary/Member
11.1.2.3	Secretary, Department of Health of the Government of Punjab or his nominee not below the rank of an officer in BPS-20, who is expert in medicine, pharmacology or pharmacy	Member
11.1.2.4	Secretary, Department of Health of the Government of Sindh or his nominee not below the rank of an officer in BPS-20, who is expert in medicine, pharmacology or pharmacy	Member
11.1.2.5	Secretary, Department of Health of the Government of Khyber Pakhtunkhwa or his nominee not below the rank of an officer in BPS-20, who is expert in medicine, pharmacology or pharmacy	Member
11.1.2.6	Secretary, Department of Health of the Government of Balochistan or his nominee not below the rank of an officer in BPS-20, who is expert in medicine, pharmacology or pharmacy	Member
11.1.2.7	Secretary, Department of Health of the Government of Gilgit Baltistan or his nominee not below the rank of an officer in BPS-20, who is expert in medicine, pharmacology or pharmacy	Member
11.1.2.8	one professor of medicine or surgery	Member
11.1.2.9	one expert in pharmaceutical manufacturing	Member
11.1.2.10	one professor of pharmacology	Member
11.1.2.11	one professor of pharmacy	Member
11.1.2.12	a co-opted expert in the field related to a specialty case before the Appellate Board	Member

11.1.3. The powers and functions of the Appellate Board are as under:-

11.1.3.1. To hear appeal preferred against the decision of the Central Licensing Board.

11.1.3.2. To hear appeal preferred against the decision of the Registration Board.

11.1.3.3. To hear appeal preferred against the authority to which the powers of the Federal Government under section 12 have been delegated related to pricing of drugs and biologicals including but not limited to Drug Pricing Committee (DPC).

11.1.3.4. To hear appeal preferred against Licensing Authority.

11.1.3.5. To hear appeals preferred against the decision of the Medical Devices Board.

11.1.3.6. To hear appeals preferred against the decision of the Enlistment Evaluation Committee.

11.1.3.7. exercise all the powers of an Inspector without restriction as to area, and such other powers as may be necessary to perform their functions

11.1.3.8. To 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.

11.1.4. Communication with the AB is through its Secretary cum member, who is Director (Legal Affairs). Division of Legal Affairs acts as a Secretariat for the AB. Matter requiring approvals/consideration of AB are forwarded to Secretary of AB for inclusion in the working paper for the AB. Working paper is circulated with the approval of the Chairman, AB, which is CEO, DRAP. Decisions are consolidated in the form of minutes of the meeting of the AB by Secretary of the AB. Decision are communicated in the form of notification of individual decisions to the relevant divisions. Correspondence with appellants and respondents is done through letters by the Legal Affairs Division, in case, information is required by the AB for further consideration. Decision so received by the relevant Division are implemented in various modes depending upon the type of decision taken by the AB i.e. Drug licensing, Pharmaceutical Evaluation & Registration, Medical Devices Board, Drug Pricing Committee, Enlistment Evaluation Committee or the Licensing Authority.

11.2. Central Licensing Board *(see section 5 of the Drugs Act, 1976)*

11.2.1. Central Licensing Board for grant of license to manufacture drugs and biologicals is constituted under Section 5 of the Drugs Act, 1976.

11.2.2. Composition of the Central Licensing Board is provided under Rule 8 of the Drugs (Licensing, Registering & Advertising) Rules, 1976. Composition of the Central Licensing Board is as under:-

S.No.	Designation	Status
11.2.2.1.	Director Drug Licensing, Drug Regulatory Authority of Pakistan	Ex-Officio Chairman
11.2.2.2.	One representative of Directorate of Quality Assurance and Laboratory Testing	Member
11.2.2.3.	The Drug Controller or Chief Inspector of Drugs of the provinces of Punjab.	Member
11.2.2.4.	The Drug Controller or Chief Inspector of Drugs of the provinces of Sindh,	Member
11.2.2.5.	The Drug Controller or Chief Inspector of Drugs of the provinces of Khyber Pakhtunkhwa	Member
11.2.2.6.	The Drug Controller or Chief Inspector of Drugs of the provinces of Balochistan	Member
11.2.2.7.	Two experts having at least fifteen years working experience in production of drugs.	Member
11.2.2.8.		Member
11.2.2.9.	Two experts of quality control or quality assurance having at least fifteen years experience of quality control or quality assurance in drugs	Member
11.2.2.10.		Member
11.2.2.11.	Two professors of pharmacy from public or private universities in Pakistan	Member
11.2.2.12.		Member
11.2.2.13.	One Law expert who shall not be below BPS-19.	Member
11.2.2.14.	The Deputy Director General (Lic.), DRAP, Islamabad	Ex-officio Secretary/ Member

11.2.3. The powers / functions of Licensing Board are as under:

11.2.3.1. To grant Drug Manufacturing licenses for drugs / biologicals.

11.2.3.2. To grant renewal of Drug Manufacturing License (DML).

11.2.3.3. To grant approval for site verification.

11.2.3.4. To grant approval of lay out plan and sections.

11.2.3.5. Cancel or suspend the manufacturing license, or withdraw permission for manufacturing of a particular section of any firm on the availability of sufficient evidence on its own motion or on the recommendation of Drugs Registration Board, if any firm is involved in the manufacture and sales of spurious drugs.

11.2.3.6. To appoint a panel of experts or inspectors of inspection of manufacturing units to submit its report to the Board.

11.2.3.7. Take actions on cases referred by the Federal Inspector of Drugs or panel of Inspectors or any authorized officer.

11.2.3.8. To appoint its subcommittees consisting of its members for the scrutiny and evaluation of applications for the grant of manufacturing licence or cases of GMP non-compliance referred by the Federal Inspector of Drugs or panel of Inspectors or any authorized officer.

11.2.3.9. Refer any case to the Expert Committee for detailed examination and evaluation.

11.2.3.10. Advise the firms for improvement or if considered necessary issue warnings and take other actions as deems fit for the purpose of improvement.

11.2.3.11. Authorize Chairperson or any of its member for performing any specific functions of Board including the disposal of day-to-day business of Board through Secretary of the Central Licensing Board or any authorized officer.

11.2.3.12. Fix the responsibility of offences before referring the case to the Drug Courts.

11.2.3.13. Members of the Licensing Board can exercise all the powers of Inspector without restriction of the area, and shall have the powers of a Provincial Inspector.

11.2.4. Communication with the LB is through its Secretary cum member, who is Additional Director (Drug Licensing). Matter requiring approvals/consideration of Licensing Board are forwarded to Secretary of

Board for inclusion in the working paper for the Licensing Board. Working paper is circulated with the approval of the Chairman, Licensing Board which is Director (PE&R). Decisions are communicated in the form of minutes of the meeting of the Licensing Board by Secretary of the Licensing Board. Decision are implemented in various modes depending upon the type of decision taken by the Licensing Board through relevant Divisions i.e. Drug licensing related matter through Licensing Division and market surveillance matters through QA&LT.

11.2.5. For smooth execution of tasks, Licensing Board has delegated, its certain powers to various tiers of the Drug Licensing Division and Quality Assurance & Laboratory Testing Division.

11.3. Registration Board *(see section 7 of the Drugs Act, 1976)*

11.3.1. Registration Board for registration of drugs and biologicals is constituted under Section 7 of the Drugs Act, 1976.

11.3.2. Composition of the Registration Board is provided under Rule 24 of the Drugs (Licensing, Registering & Advertising) Rules, 1976. Composition of the Board is as under:-

S. No	Designation	Status
11.3.2.1.	Director PE&R	Ex-officio Chairman
11.3.2.2.	Additional Director PE&R	Secretary/Member
11.3.2.3.	Representatives of Biological Evaluation Research	Member
11.3.2.4.	Representatives of Medical Devices	Member
11.3.2.5.	Representatives of Quality Assurance & Laboratory Testing Division	Member
11.3.2.6.	Director Drug Testing Laboratories Punjab	Member
11.3.2.7.	Director Drug Testing Laboratories Sindh	Member
11.3.2.8.	Director Drug Testing Laboratories Khyber Pakhtunkhwa	Member

11.3.2.9.	Director Drug Testing Laboratories Baluchistan	Member
11.3.2.10.	Representative of Intellectual Proprietary Organization, Pakistan	Member
11.3.2.11.	Law expert, Ministry of Law & Justice	Member
11.3.2.12.	Pharmacologist	Member
11.3.2.13.	Physician	Member
11.3.2.14.	Expert in Biological Drugs	Member
11.3.2.15.	Expert in Drug Manufacturing	Member
11.3.2.16.	Expert in Hospital Pharmacy	Member
11.3.2.17.	Expert in Veterinary Medicines	Member
11.3.2.18.	Expert in Biologicals	Member
11.3.2.19.	Expert in Pharmacology	Member
11.3.2.20.	Expert in Hospital Pharmacy	Member
11.3.2.21.	Representatives of Pharma Bureau, Pakistan Pharmaceutical Manufacture's Association, Pakistan Chemist & Druggist Association, Consumer Association	Observers

11.3.3. The powers / functions of Registration Board are as under:

11.3.3.1. To grant registration / marketing authorization for drugs / biologicals to be used in Pakistan.

11.3.3.2. To grant registration for finished drugs / biologicals for export purpose.

11.3.3.3. To grant renewal of registrations of drug / biologicals.

11.3.3.4. To grant contract manufacturing permissions.

11.3.3.5. To grant extension in contract manufacturing permission.

11.3.3.6. To cancel or suspend the registration / contract manufacturing permission of drugs / biologicals.

11.3.3.7. Approval for post registration variations including:

11.3.3.7.1. Relaxation / exemption in urdu version only for drugs imported for critical ailments like AIDS, cancer, vaccines, sera sutures etc subject to the condition that same shall be printed at any licensed premises prior to marketing.

11.3.3.7.2. Relaxation / exemption in urdu version only for drugs to be imported in low volume by the firms having manufacturing facility in Pakistan subject to the condition that same shall be printed at any licensed premises prior to market.

11.3.3.7.3. Change of name of the manufacturer of imported drugs.

11.3.3.7.4. Increase/ decrease in shelf life of finished drug.

11.3.3.7.5. Grant of additional packing of already registered drugs/medicines except injectables.

11.3.3.7.6. Change of packing from PVC to Alu-Alu, strip to blister/bottle and vice-versa etc.

11.3.3.7.7. Changes of source of API-intermediates (pellets/ liquid) and excipients of registered drugs.

11.3.3.7.8. Change in the packing design/packaging components/ change in label, carton/change in shape, colour of Capsule, Tablets and shape of blister/ aluminum foil.

11.3.3.7.9. Change of brand names of registered drugs

11.3.3.7.10. Change of contract manufacturer.

11.3.3.8. To initiate action on safety of drugs.

11.3.3.9. To constitute panel of inspector for product specific inspection, GMP inspection etc. before grant of registrations.

11.3.3.10. To recommend actions to the Licensing Board against the manufactures failed to comply with the GMP regulations.

11.3.3.11. To appoint its subcommittees consisting of its members for the scrutiny and evaluation of applications for the grant of registration, or cases referred by Federal Inspector of Drugs or any authorized officer.

11.3.3.12. Refer any case to the Expert Committee for detailed examination and evaluation.

11.3.3.13. Authorize Chairperson or any of its member for performing any specific functions of Board including the disposal of day-to-day

business of Board through Secretary of the Central Licensing Board or any authorized officer.

11.3.3.14. Members of the Registration Board can exercise all the powers of Inspector without restriction of the area, and shall have the powers of a Provincial Inspector.

11.3.4. Communication with the Registration Board is through its Secretary cum member, who is Additional Director (PE&R). Matter requiring approvals/consideration of Registration Board are forwarded to Secretary of Board for inclusion in the working paper for the Registration Board. Working paper is circulated with the approval of the Chairman, Registration Board which is Director (PE&R). Decisions are communicated in the form of minutes of the meeting of the Registration Board by Secretary of the Registration Board. Decision are implemented in various modes depending upon the type of decision taken by the Registration Board through relevant Divisions i.e. Registration issuance related matter through PE&R/BD and market surveillance matters through QA&LT.

11.3.5. For smooth execution of tasks, Registration Board has delegated, its certain powers to various tiers of the Pharmaceutical Evaluation & Registration Division, Biological Drugs & Quality Assurance and Laboratory Testing Division.

11.4. Medical Devices Board *(see Rule 59 (1) of the Medical Devices Rules, 2017)*

11.4.1. Medical Devices Board for licensing establishments and enlistment/registration of medical devices is constituted under Rule 59 (1) of the Medical Devices Rules, 2017.

11.4.2. Composition of Medical Devices Board is provided under Rule 59(2) of the aforesaid rules. Composition of the Board is as under:-

S.No	Designation	Status
11.4.2.1.	Director, Medical Devices and Medicated Cosmetics, Drug Regulatory Authority of Pakistan	Ex- Officio Chairman
11.4.2.2.	Additional Director, Medical Devices and Medicated Cosmetics, Drug Regulatory Authority of Pakistan	Secretary/Member

11.4.2.3.	Director General Health or his nominee not below BS19, of Punjab	Member
11.4.2.4.	Director General Health or his nominee not below BS19, of Sindh	Member
11.4.2.5.	Director General Health or his nominee not below BS19, of Khyber Pakhtunkhawa	Member
11.4.2.6.	Director General Health or his nominee not below BS19, of Balochistan	Member
11.4.2.7.	Director General Health or his nominee not below BS19, of Gilgit-Baltistan	Member
11.4.2.8.	One urologist or nephrologists having relevant experience of not less than five years	Member
11.4.2.9.	Two pharmacists having relevant experience of not less than five years in manufacturing or quality control of therapeutic goods preferably in medical devices	Member
11.4.2.10.		Member
11.4.2.11.	One biomedical engineer having relevant experience of not less than five years	Member
11.4.2.12.	One radiologist having relevant experience of not less than five years	Member
11.4.2.13.	One software or electromechanical engineer having relevant experience of not less than five years	Member
11.4.2.14.	One general or orthopedic surgeon having relevant experience of not less than five years	Member
11.4.2.15.	One cardiovascular surgeon or interventional cardiologist having relevant experience of not less than five years	Member
11.4.2.16.	One hospital pharmacist having relevant experience of not less than five years	Member

11.4.2.17.	One pathologist or medical technologist having relevant experience of not less than five years	Member
11.4.2.18.	Co-opt expert of any specialty for the disposal of relevant cases.	
11.4.2.19.	One representative each from association of manufacturers and importers (Healthcare Devices Association of Pakistan or Pakistan Chemists and Druggists Association or Pharma Bureau) as observers as and when required.	

11.4.3. Medical Devices Board has following powers and functions to:-

11.4.3.1. To grant establishment licenses to manufacture medical devices.

11.4.3.2. To grant enlistment/ registration of medical devices to be used in Pakistan.

11.4.3.3. To grant enlistment/ registration of medical devices for export purpose.

11.4.3.4. To grant renewal of enlistment/ registration of medical devices.

11.4.3.5. To grant permissions for outsourcing.

11.4.3.6. To grant extension in permissions for outsourcing.

11.4.3.7. To cancel or suspend the establishment license, enlistment/ registration of medical devices / permissions for outsourcing of medical devices/ import & export permits of medical devices.

11.4.3.8. To fix responsibility of offences before referring a case to the Court.

11.4.3.9. Appoint a panel of experts or inspectors for inspection of any premises for grant of establishment license or any establishment any for enlistment or registration of medical devices within the country or abroad.

11.4.3.10. To extend the sealing period not exceeding three months of the licensed establishment on the request of the Inspector for the purpose of investigation

11.4.3.11. To advise the establishment for improvement or, if considered necessary, issue warning or take other action as it may deem fit for the purpose of improvement.

11.4.3.12. To recommend to the appropriate authority to restrict or stop the import of any medical device or classes of medical devices, which are produced in sufficient quantity in Pakistan.

11.4.3.13. To initiate action on safety of medical devices.

11.4.3.14. To control advertisement of medical devices.

11.4.3.15. To perform import & export related activities of medical devices including import under donation, and for hospital & personal use.

11.4.3.16. Issuance of GMP certificate and Free Sale Certificate (FSC) for medical devices.

11.4.3.17. To delegate any of its powers to any authorized officer to perform functions as are assigned to MDB.

11.4.4. Communication with the Medical Devices Board is through its Secretary cum member, who is Additional Director (MDMC). Matter requiring approvals/consideration of MDB are forwarded to Secretary of Board for inclusion in the working paper for the MDB. Working paper is circulated with the approval of the Chairman, MDB which is Director (MDMC). Decisions are communicated in the form of minutes of the meeting of the MDB by Secretary of the Medical Devices Board. Decision are implemented in various modes depending upon the type of decision taken by the MDB through relevant Divisions i.e. licensing establishments/ enlistment/Registration issuance related matter through MDMC and market surveillance matters through QA&LT.

11.4.5. For smooth execution of tasks, MDB has delegated, its certain powers to various tiers of the MDMC & QA&LT Division.

11.5. Enlistment Evaluation Committee: *(see Rule 7(1) of the Alternative Medicines and Health Products (Enlistment) Rules, 2014)*

11.5.1. Enlistment Evaluation Committee for enlistment of establishments and enlistment of alternative medicines and health products is constituted under Rule 7(1) of the Alternative Medicines and Health Products (Enlistment) Rules, 2014.

11.5.2. Composition of Enlistment Evaluation Committee is as under:-

S.No	Designation	Status
11.5.2.1.	Director Health and OTC Products	Chairperson / Member
11.5.2.2.	Deputy DG Health and OTC Products	Vice Chairperson / Member
11.5.2.3.	Chief Drug control and Traditional Medicine Division NIH	Member
11.5.2.4.	Chief Nutrition Division NIH	Member

11.5.2.5.	One Expert of homeopathy nominated by Authority	Member
11.5.2.6.	One expert of quality control nominated by Authority.	Member
11.5.2.7.	One expert of unani nominated by Authority	Member
11.5.2.8.	Deputy Drugs Controller Health and OTC Products	Secretary/Member

11.5.3. Enlistment Evaluation Committee has following powers and functions to:-

11.5.3.1. To grant provisional certificate for as manufacturer or importer of alternative medicines and health products.

11.5.3.2. To grant provisional certificate for enlistment of alternative medicines and health products to be used in Pakistan.

11.5.3.3. To grant provisional certificate for enlistment of alternative medicines and health products for export purpose.

11.5.3.4. To reject the application for product enlistment recording reasons thereof.

11.5.3.5. To grant certificate for carrying out contract manufacturing of alternative medicines or health products on behalf of enlistment holder or licensees.

11.5.3.6. To revoke or suspend the provisional certificate for enlistment as manufacturer or importer, enlistment of alternative medicines and health products / contract manufacturing permission of alternative medicines and health products / import & export permits of alternative medicines and health products.

11.5.3.7. To fix responsibility of offences before referring a case to the Court.

11.5.3.8. To verify contents or information provided in the application dossier through panel of Inspectors or any authorized Inspector of Authority or Provincial Inspector for inspection of any premises for grant of provisional Certificate for Enlistment as Manufacturer or Importer, enlistment of alternative medicines & health products, and contract manufacturing permission of alternative medicines & health products

11.5.3.9. To direct the applicants for explanation about any matter or refer the matter to experts of relevant specialty for expert opinion.

11.5.3.10. To issue a show cause notice or a notice for personal hearing to decide the cases of violation.

11.5.3.11. Issuance of GMP certificate and Free Sale Certificate for alternative medicines and health products.

11.5.3.12. To delegate any of its powers to any authorized officer to perform functions as are assigned to EEC.

11.5.4. Communication with the EEC is through its Secretary cum member, who is Deputy Director (H&OTC). Matter requiring approvals/consideration of EEC are forwarded to Secretary of Committee for inclusion in the working paper for the EEC. Working paper is circulated with the approval of the Chairman, EEC which is Director (H&OTC). Decisions are communicated in the form of minutes of the meeting of the EEC by Secretary of the Enlistment Evaluation Committee. Decision are implemented in various modes depending upon the type of decision taken by the EEC through relevant Divisions i.e. licensing establishments / enlistment / issuance related matter through H&OTC and market surveillance matters through QA&LT.

11.5.5. For smooth execution of tasks, certain powers of EEC has been delegated to various tiers of the H&OTC & Quality Assurance and Laboratory Testing Division.

11.6. **Drug Pricing Committee** *(see Section 10 and Sub-Section 3 of Section 12 of the Drugs Act, 1976)*

11.6.1. Drug Pricing Committee for recommendations of prices of drugs / biologicals to the Federal Government is constituted under Section 10 and Sub-Section 3 of Section 12 of the Drugs Act, 1976.

11.6.2. Composition of Drug Pricing Committee is as under:-

S.No	Designation	Status
11.6.2.1.	Director Costing & Pricing, Drug Regulatory Authority of Pakistan	Chairperson
11.6.2.2.	Secretary, Department of Health of the Government of Punjab or his nominee not below the rank of an officer in BPS-19	Member
11.6.2.3.	Secretary, Department of Health of the Government of Sindh or his nominee not below the rank of an officer in BPS-19	Member
11.6.2.4.	Secretary, Department of Health of the Government of Khyber Pakhtunkhwa or	Member

	his nominee not below the rank of an officer in BPS-19	
11.6.2.5.	Secretary, Department of Health of the Government of Balochistan or his nominee not below the rank of an officer in BPS-19	Member
11.6.2.6.	Secretary, Department of Health of the Government of Gilgit Baltistan or his nominees not below the rank of an officer in BPS-19	Member
11.6.2.7.	Chief Cost Accountant Officer or Cost Accountant, Ministry of Finance, Government of Pakistan	Member
11.6.2.8.	Deputy Director General (Pricing) / Deputy Drugs Controller (Pricing), Drug Regulatory Authority of Pakistan	Secretary
11.6.2.9.	Representative of Pakistan Medical Association.	Co-opted Member
11.6.2.10.	Representative of Consumer Rights Commission of Pakistan	Co-opted Member
	Representative of Pharma Bureau.	Observer
11.6.2.11.	Representative of Pakistan Pharmaceutical Manufacturers Association.	Observer

11.6.3. Drug Pricing Committee has following Terms of References:-

11.6.3.1. To fix and review the Maximum Retail Price at which a drug / biological is to be sold subject to approval by the Federal Government.

11.6.3.2. To advise the Federal Government on matters related to drug pricing.

11.6.3.3. To monitor availability of drugs at approved prices throughout the country.

11.6.3.4. To give such directions to the provincial governments and the Federal Inspectors of Drugs for price monitoring and availability at approved prices.

11.6.3.5. To issue orders for actions in case of contraventions of Drugs Act and the Act regarding pricing matters.

11.6.4. Communication with the Drug Pricing Committee is through its Secretary, who is Deputy Director (C&P Division). Matter requiring consideration/recommendations of DPC are forwarded to Secretary of Committee for inclusion in the working paper for the Drug Pricing Committee. Working paper is circulated with the approval of the Chairman, DPC which is Director (C&P). Decisions / Recommendations are recorded in the form of minutes of the meeting of the DPC. The recommendations of the DPC are forwarded in the form of summaries through M/o NHSR&C to the FG for approval. Decisions are received in the form of minutes of FG. Decision of the FG are published in the Gazette Notification by the C&P Division and are also communicated to the relevant Division. Decisions are communicated by relevant Divisions i.e. MRP related matters of already registered products through C&P and new registrations by PE&R / BD Divisions by issuing notified MRP, and market surveillance matters through QA&LT.

11.7. National Price Fixation Committee for Life Saving Medical Devices (LSMDs)

(Notification dated 8th September, 2020)

11.7.1. National Price Fixation Committee for Life Saving Medical Devices (LSMDs) is constituted under the directions of Honorable Supreme Court of Pakistan through for price fixation of Life Saving Medical Devices which were previously determined by the National Interventional Cardiology Board (NICB).

11.7.2. Composition of National Price Fixation Committee for LSMDs is as under:-

Sr.no	Designation	Status
11.7.2.1.	Chairman, National Interventional Cardiology Board (NICB),	Chairman
11.7.2.2.	Director Clinical Governance & Organizational Standards, Healthcare Commission, Punjab, Lahore	Member
11.7.2.3.	Executive Officer, Sindh Healthcare Commission, Karachi	Member
11.7.2.4.	Director Operation, Khyber Pakhtunkhwa Healthcare Commission, Peshawar	Member
11.7.2.5.	Representative of Baluchistan Healthcare Commission, Quetta.	Member

11.7.2.6.	Pakistan Society of International Cardiology	Member
11.7.2.7.	Deputy Executive Director, Federal Government Polyclinic Hospital, Islamabad.	Member
11.7.2.8.	Director (Costing & Pricing) Drug Regulatory Authority of Pakistan (DRAP), Islamabad.	Member / Secretary

11.7.3. National Price Fixation Committee for LSMDs has following Terms of References:

11.7.3.1. To fix and review the maximum prices of different categories of Life Saving Medical Devices based on overage procurement prices obtained through the central procurement formula, subject to approval of the Federal Government; and

11.7.3.2. To advise the Federal Government on matters related to prices of different categories of Life Saving Medical Devices.

11.7.4. Communication with the National Price Fixation Committee for LSMDs is through its Secretary, who is Director (C&P Division). Matter requiring consideration/recommendations of National Price Fixation Committee for LSMDs are forwarded to Secretary of Committee for inclusion in the working paper for the Committee. Working paper is circulated with the approval of the Chairman, National Price Fixation Committee for LSMDs which is Chairman, National Interventional Cardiology Board. Decisions / Recommendations are recorded in the form of minutes of the meeting of the National Price Fixation Committee for LSMDs. The recommendations of the National Price Fixation Committee for LSMDs are forwarded in the form of summaries through M/o NHSR&C to the FG for approval. Decisions are received in the form of minutes of FG. Decision of the FG are published in the Gazette Notification by the C&P Division and are also communicated to the MDMC Division. Decisions are communicated by MDMC Division by issuing notified price for enlisted/ registered medical devices.

11.8. Committee on Advertisement *(see Section 10 of the Drugs Act, 1976)*

11.8.1. Committee on Advertisement (CoA) for recommendations of approval of advertisements to the Federal Government is constituted under Section 10 of the Drugs Act, 1976.

11.8.2. Composition of Committee on Advertisement is as under:-

S. No.	Designation	Status
11.8.2.1.	Director (Pharmacy Services), Drug Regulatory Authority of Pakistan, Islamabad.	Chairman (*Ex-Officio*)
11.8.2.2.	Representative from Directorate of Health and OTC Products, not below an officer of BPS-18, Drug Regulatory Authority of Pakistan	Member
11.8.2.3.	Representative from Directorate of Pharmaceutical Evaluation and Registration, not below an officer of BPS-18, Drug Regulatory Authority of Pakistan	Member
11.8.2.4.	Representative from Directorate of Medical Devices and Medicated Cosmetics, not below an officer of BPS-18, Drug Regulatory Authority of Pakistan	Member
11.8.2.5.	Representative from Pakistan Electronic Media Regulatory Authority (PEMRA), not below an officer of BPS-18.	Member
11.8.2.6.	Representative from Health Services Academy, not below an officer of BPS-18.	Member
11.8.2.7.	A Co-opted expert in the field related to a specialty case before the committee.	Member
11.8.2.8.	Deputy Drugs Controller, Pharmacy Services, Drug Regulatory Authority of Pakistan.	Secretary of the Committee (*Ex-Officio*)

11.8.3. The terms of reference of the CoA are as under; -

11.8.3.1. To evaluate application preferred under Rule 31 of the Drugs (LRA) Rules, 1976 and to approve the advertisement in accordance with the said rule and with such other conditions, as may be required in public interest;

11.8.3.2. To regulate the advertisements of therapeutic goods or a remedy or a treatment or offer of a treatment for any disease and to enforce regulations for the advertisement;

11.8.3.3. To monitor and investigate the complaints received from various quarters and issue orders to the actions to be taken in respect of any contraventions of the Drugs Act and the Act, regarding advertisement matters referred to it by Federal Inspectors;

11.8.3.4. To call any person for personal hearing to adduce evidence before the Committee on Advertisement; and

11.8.3.5. To issue guidelines with the prior approval of the Drug Regulatory Authority of Pakistan for regulating the advertisement of therapeutic goods.

11.8.4. Communication with the Committee on Advertisement is through its Secretary, who is Deputy Director (Pharmacy Services Division). Matters requiring consideration for CoA are forwarded to Secretary of the CoA for inclusion in the working paper / agenda for the Committee. Working paper is circulated with the approval of the Chairman, Committee on Advertisement which is Director (Pharmacy services). Decisions / Recommendations are recorded in the form of minutes of the meeting of the CoA. The recommendations of the CoA are forwarded in the form of summaries through M/o NHSR&C to the FG for approval. Decisions are received in the form of minutes of FG. Decision are communicated to the relevant applicants / stakeholders by Pharmacy Services and for surveillance activities through QA&LT.

11.9. Clinical Studies Committee (CSC) *(see Rule 13(1) of the Bio-Study Rules, 2017)*

11.9.1. Clinical Studies Committee for grant of license for clinical trial sites, BA or BE studies center and Contract Research Organization (CRO) and approval or registration of clinical trials and BA or BE studies is constituted under Rule 13(1) of the Bio-Study Rules, 2017.

11.9.2. Composition of Clinical Studies Committee is as under:-

S. No.	Designation	Status
11.9.2.1.	Director, Division of Pharmacy Services, DRAP	Chairman (*Ex-Officio*)
11.9.2.2.	Additional Director or Deputy Director, Division of Pharmacy Services, DRAP	Secretary(*Ex-Officio*)
11.9.2.3.	Chairman, Pakistan Health Research Council or his nominee	Member

	who may be directly involved in conduct of clinical trials or having experience of conducting clinical trials	
11.9.2.4.	one clinical pharmacist, from a renowned hospital, having at least five years of experience,	Member
11.9.2.5.	one professor of pharmacology,	Member
11.9.2.6.	one professor of pharmacy, having background of bio-pharmaceutics	Member
11.9.2.7.	one clinician or physician or medical specialist having at least fifteen years of experience,	Member
11.9.2.8.	one statistician, having background of designing and evaluating clinical studies with five years of experience or pharmaceutical professional having five years of experience in educational or professional services or practice of statistics,	Member
11.9.2.9.	one representative of Pakistan pharmaceutical manufacturer association and the Pharma Bureau, each having fifteen years of experience and expertise of conducting clinical trials and BA or BE studies; and	Observer
11.9.2.10.	Co-opted member for therapeutic goods or any other specific matter	Co-opted member

11.9.3. Powers and functions of the CSC are as under; -

11.9.3.1. Screening, assessment, review and evaluation of applications for license of clinical trials, clinical trial sites, BA or BE studies, center and CRO;

11.9.3.2. Screening, assessment, review and evaluation of applications for approval or registration of clinical trials and BA or BE studies;

11.9.3.3. Inspection of the premises prior to grant of license, approval of clinical trial, BA or BE study and during and after the completion

of the trial or study, if so desired, by a panel constituted by the CSC and any co-opted member under sub-rule (6) of rule 13, any site where clinical trial and BA or BE study is planned to be conducted, to satisfy itself of the observance of conditions, guidelines or criteria as notified by the DRAP;

11.9.3.4. Grant, reject or suspend approval of a clinical trial and BA or BE study;

11.9.3.5. Grant, reject or suspend a license to center, clinical trial site, CRO and laboratory.

11.9.3.6. Evaluate the continuing review report on clinical trials and BA or BE studies submitted periodically by the IRB, sponsor, CRO or investigator and centers, as the case may be.

11.9.3.7. Renewal or extension of approval or registration to a clinical trial and BA or BE study.

11.9.3.8. Renewal of license to center, clinical trial site, CRO and laboratory.

11.9.3.9. To constitute a sub-committee for the performance of any of its functions.

11.9.3.10. Co-opt any subject related expert person having vast experience in the relevant field for advice on any particular matter under consideration.

11.9.3.11. Delegate any of its powers to Chairman of the Committee in writing with appropriate justification.

11.9.4. Communication with the Committee on Advertisement is through its Secretary, who is Additional Director / Deputy Director (PS Division). Matter requiring consideration for CSC are forwarded to Secretary CSC for inclusion in the working paper / agenda for the Committee. Working paper is circulated with the approval of the Chairman, CSC which is Director (PS). Decisions / Recommendations are recorded in the form of minutes of the meeting of the CSC. Decisions are communicated in the form of minutes of CSC. Decision are communicated to the relevant applicants / stakeholders by relevant Divisions i.e. Pharmacy Services.

11.10. **Committee of Experts on Drug Research** *(see Rule 8(1) of The Drugs (Research) Rules, 1978)*

11.10.1. Committee of Experts on Drug Research for utilization of Research and Development Fund is constituted under Rule 8(1) of The Drugs (Research) Rules, 1978.

11.10.2. Composition the Committee is provided under Rule 8(3) of the aforesaid Rules and is as under:-

S. No.	Designation	Status
11.10.2.1.	Director, Division of Pharmacy Services, DRAP	Chairman (*Ex-Officio*)
11.10.2.2.	Deputy Director, Division of Pharmacy Services, DRAP	Secretary cum member
11.10.2.3.	Chairman, Pakistan Council of Scientific and Industrial Research or his nominee not below the rank of BPS-19 who shall directly be responsible for drug research activities.	Member
11.10.2.4.	Chairman, Pakistan Medical Research Council or his nominee not below the rank of BPS-18 who shall directly be responsible for drug research activities.	Member
11.10.2.5.	Chairman, Higher Education Commission or his nominee not below the rank of BPS-19 who shall directly be responsible for drug research activities.	Member
11.10.2.6.	One Professor of Pharmacy from Punjab;	Member
11.10.2.7.	One Professor of Pharmacy from Sindh;	Member
11.10.2.8.	One Professor of Pharmacy from KPK;	Member
11.10.2.9.	One Professor of Pharmacy from Balochistan;	Member
11.10.2.10.	One Professor of Pharmacy from GB;	Member
11.10.2.11.	One expert in biotechnology not below the rank of BPS-19.	Member
11.10.2.12.	Co-opted expert in the field related to a specialty case before the committee.	Member

11.10.3. Powers and functions of the Committee of Experts on Drug Research are as under:-

11.10.3.1. To advise the Federal Government on the utilization of the Research and Development Fund obtained from pharmaceutical companies under Section 12(1)(b) of the Drugs Act.

11.10.3.2. To determine the priorities in drug research.

11.10.3.3. To evaluate the applications received for the grant in aid from Central Research Fund and make allocations from the Central Research Fund for approval from Federal Government.

11.10.3.4. To give directions in drug research.

11.10.3.5. To take or propose such actions and measures as may be necessary for ensuring effective and proper use of the Fund.

11.10.3.6. To send an expert or a panel of experts to visit the premises at which the research is being conducted and to see that the Fund is being utilized in accordance with the approved plan

11.10.3.7. To make recommendations to Federal Government, at any stage of an investigation, to withdraw the aid from the recipient and to terminate a clinical trial.

11.10.4. Communication with the Committee of Experts on Drug Research is through its Secretary, who is Deputy Director (PS Division). Matters requiring consideration for Committee of Experts on Drug Research are forwarded to Secretary of the Committee for inclusion in the working paper / agenda for the Committee. Working paper is circulated with the approval of the Chairman, Committee of Experts on Drug Research which is Director (PS). Decisions / Recommendations are recorded in the form of minutes of the meeting of the Committee of Experts on Drug Research. The recommendations of the Committee of Experts on Drug Research are forwarded in the form of summaries through M/o NHSR&C to the FG for approval. Decisions are received in the form of minutes of FG. Decision are communicated to the relevant applicants / stakeholders by Pharmacy Services Division and for surveillance activities through QA&LT.

11.11. **Pharmacovigilance Risk Assessment Expert Committee (PRAEC)** *(see Rule 9 of the the Pharmacovigilance Rules-2022)*

11.11.1. Pharmacovigilance Risk Assessment Expert Committee is constituted under Rule 9 of thePharmacovigilance Rules 2022. Authority has notified the PRAEC for evaluation of risks associated with the use of therapeutic goods, signal detection, causality assessment, risk management, risk minimization, failure mode effect analysis and evaluation of periodic reports.

11.11.2. The composition of PRAEC as per the Rule 9(3) of the the Pharmacovigilance Rules 2022, is as under:

S. No.	Designation	Status
11.11.2.1.	To be notified by DRAP from the members of PRAEC for three years i.e. tenure of the Committee;	Chairman
11.11.2.2.	Director, Division of Pharmacy Services, ;	Ex-Officio Co-Chair
11.11.2.3.	Additional / Deputy Director, Division of Pharmacy Services, or pharmacovigilance;	Ex-OfficioSecretary
11.11.2.4.	One professor of pharmacy practice;	Member
11.11.2.5.	Expert of basic pharmacology having at least ten-year experience;	Member
11.11.2.6.	Expert of clinical pharmacology having at least ten-year experience;	Member
11.11.2.7.	Expert of clinical pharmacy or clinical pharmacist having at least ten-year experience in hospital;	Member
11.11.2.8.	Expert of medicine / medical specialist having at least ten-year experience in hospital;	Member
11.11.2.9.	Expert of epidemiology or pharmacoepidemiology having at least ten-year experience;	Member
11.11.2.10.	Expert of toxicology or forensic medicines having at least ten-year experience;	Member
11.11.2.11.	Expert of pharmacovigilance having at least ten-year experience in conduct of pharmacovigilance activities;	Member

11.11.2.12.	Expert of clinical trials or drug research having at least ten-year experience;	Member
11.11.2.13.	Expert of biologicals having at least ten-year experience; and	Member
11.11.2.14.	Expert of biostatistics having at least ten-year experience.	Member

11.11.3. The functions of PRAEC as per Rule 10(1) of the Pharmacovigilance Rules shall be as follows:-

11.11.3.1. Cover all aspects of risk management associated with the use of therapeutic goods, i.e. signal detection, assessment, risk minimization and communication related to risks of adverse drug reaction, Perform the initial analysis and prioritization of signals which are detected and validated by NPC;

11.11.3.2. On the basis of concerns resulting from the evaluation of data from Pharmacovigilance activities, recommend to the PNPC to inform the Provincial Pharmacovigilance centres or health department, Pakistan Medical and Dental Council, Pakistan Medical Association, Pharmacy Council, Nursing Council or general public through web-based safety announcement, therapeutic good safety alerts, and healthcare advisory, where it considers necessary that a new contraindication, a reduction in the recommended dose or a restriction to the indication of therapeutic goods is necessary;

11.11.3.3. Verify whether the safety concern relate to therapeutic goods other than the one covered by the information, or whether it is common to all products belonging to the same range or therapeutic class and if identifies that safety concerns relate to more therapeutic goods than those which are covered by the information or that is common to all therapeutic goods belonging to the same range or therapeutic class, it shall extend the scope of procedure accordingly;

11.11.3.4. Evaluate and assess DSUR, PBRER and RMP or nominate a penal of expert or appoint rapporteur for this purpose;

11.11.3.5. On the basis of assessment and evaluation of database, or due to detection of new signals if it is found that risks of

therapeutic goods outweigh its benefits, it shall recommend a regulatory or necessary remedial action to the concerned board, committee or Division for variation, suspension, revocation, market withdrawal, change in safety specification or any other action which it considers appropriate to ensure therapeutic good safety;

11.11.3.6. Recommend to Registration Board to impose obligations on manufacturer or registration holder of drug to conduct post authorization or registration safety or efficacy studies, if it is found that during the evaluation of data, there is a safety concern with the use of drug;

11.11.3.7. In the case of assessment and evaluation of PBRER, DSUR, RMP and final report PASS and post-authorization efficacy study or report of rapporteur, if it is found that there is risk associated with the drug, PRAEC may recommends regulatory action to the concerned board, committee or division, which may include suspension of license, revocation and cancellation of registration, market withdrawal, change in label or safety specification;

11.11.3.8. Shall consider or recognize and if deem appropriate shall implement within Pakistan the pharmacovigilance relevant decisions of other countries and of regional and international bodies of the following nature, namely;-

11.11.3.9. Modification or removal of an approved indication of therapeutic good due to safety reason;

11.11.3.9.1. Addition of contraindications;

11.11.3.9.2. Imposition of post-authorization safety or efficacy studies due to safety reasons;

11.11.3.9.3. Major changes in the statements of warning, precaution or adverse reactions in the product information;

11.11.3.9.4. Withdrawal or suspension of therapeutic good in other countries due to safety reason; and

11.11.3.9.5. Any other safety information or decision which it considers appropriate, for ensuring the safety of the public;

11.11.3.10. Recommend to the concerned board or committee to approve or amend the safety specifications and label

information based upon Pharmacovigilance evaluations; and

11.11.3.11. Nominate a team for GVP inspection of manufacturers or registration holders of therapeutic goods.

11.11.4. Communication with the PRAEC is through its Secretary, who is Additional Director / Deputy Director (PS Division). Matters requiring consideration for PRAEC are forwarded to Secretary of the aforesaid committee for inclusion in the working Paper / agenda for the Committee. Working paper is circulated with the approval of the Chairman, PRAEC. Decisions / recommendations are recorded in the form of minutes of the meeting of the PRAEC Committee. Decision are communicated to the concerned Board, Committee or Division and uploaded on the website as an alert and communicated to stakeholders if required.

11.12. **Committee for Allocation of Quota of Controlled Substances (CAQCS)** *(see clause (iv) of Rule 2 of the Control of Narcotic Substances (regulation of drugs of abuse, controlled chemicals, equipment and materials) Rules, 2001)*

11.12.1. Committee for Allocation of Quota of Controlled Substances (CAQCS) has been constituted under clause (iv) of Rule 2 of the Control of Narcotic Substances (regulation of drugs of abuse, controlled chemicals, equipment and materials) Rules, 2001.

11.12.2. The composition of the Committee for Allocation of Quota of Controlled Substances (CAQCS) is as under:

S. No.	Designation	Status
11.12.2.1.	Secretary, M/o Narcotics Control	Chairman
11.12.2.2.	Director General Anti-Narcotics Force (ANF) or his nominee	Member
11.12.2.3.	Director (Controlled Drugs), DRAP	Member cum-Secretary

11.12.3. Following is the functions of the Committee for Allocation of Quota of Controlled Substances (CAQCS):

11.12.3.1. To allocate quota of controlled substances i.e. narcotic drugs, psychotropic substances and precursor chemicals.

11.12.3.2. To constitute panels for inspection of facilities for verification of consumption of controlled substances i.e. narcotic drugs, psychotropic substances and precursor chemicals.

11.12.3.3. To constitute panels for destruction of controlled substances i.e. narcotic drugs, psychotropic substances and precursor chemicals.

11.12.3.4. Allied matters related to the controlled substances i.e. narcotic drugs, psychotropic substances and precursor chemicals

11.12.4. Communication with the CAQCS will be through its Secretary, who is Director (Controlled Drugs Division). Matters requiring consideration for CAQCS will be forwarded to Secretary of the aforesaid committee for inclusion in the Working Paper / agenda for the Committee. Working paper is circulated with the approval of the Chairman, CAQCS. Decisions are recorded in the form of minutes of the meeting of the CAQCS Committee. Decision are communicated to the relevant applicants / stakeholders by Controlled Drugs Division. Surveillance activities are conducted through ANF and / or QA&LT Division.

12. Licensing Authority (Notification No.F.7-3/2011-I&E(Pt))

12.1. CEO DRAP is the Licensing Authority to perform the import & export related activities of therapeutic goods. The functions of the Licensing Authority under Drugs (I&E) Rules, 1976 are as under:

12.1.1. License to import drug other than the finished drugs.

12.1.2. License to Import small quantities of drugs for the purpose of clinical trial, examination, test or analysis.

12.1.3. Signing of invoices for clearance of imported registered finished drug products.

12.1.4. Signing of invoices and issuance of certificate for clearance of imported raw materials and excipients.

12.1.5. Issuance of No Objection Certificate for export of finished drugs.

12.1.6. Personal use NOCs for import or export of drugs under Drugs (I&E) Rules, 1976.

12.1.7. Issuance of NOCs under special SRO (for import of un-registered/Non available medicines by hospitals and institutions).

12.1.8. Issuance of NOCs under special SRO (for import of medicines as donation by agencies).

12.1.9. License to export drug other than the finished drugs.

12.2. For smooth execution of tasks, Licensing Authority has delegated its powers to various tiers of QA&LT Division and all the communication related to import and export activities of drugs is carried out through the authorized field offices of DRAP located in all provincial headquarters and Islamabad Capital Territory. Matters requiring approval of the Licensing Authority are referred to QA&LT division at headquarter for approval / consideration of the Licensing Authority and communication is made by the QA&LT Division accordingly.

13. Provincial Governments (see section 44 of the Drugs Act, 1976)

13.1. PG is consisting of the Chief Minister and Provincial Ministers, which shall act through the Chief Minister. Under the Act, PG have following roles and responsibilities in the operations of the regulations of therapeutic goods:-

13.1.1. Regulation of sale, storage and distribution of therapeutic goods under section 6 of the Drugs Act through promulgation of rules in respect of the following:-

13.1.1.1. The establishment of laboratories for testing and analyzing drugs;

13.1.1.2. The qualifications and the procedure, for exercise of powers and performance of functions of Provincial Inspectors;

13.1.1.3. The forms of reports to be given by Government Analysts and the manner of application for test or analysis and the fees payable therefor;

13.1.1.4. The conditions to regulate sale or storage or distribution of drugs or any specific drug or class of drugs;

13.1.1.5. The offences against this Act or any rule in relation to which the stock of drugs shall be liable to confiscation and destruction under this Act;

13.1.1.6. The forms of licences for the sale or distribution of drugs or any specified drug or class of drugs, the authority empowered to issue the same, the form of applications for such licences, the fees payable therefor and the condition subject to which such licences may be issued;

13.1.1.7. The procedure to be followed by the Provincial Quality Control Board; and

13.1.1.8. Any other matter allied to their mandate.

13.1.2. Constitution of the Appellate Authority for disposal of appeals filed against decision of Provincial Quality Control Board.

13.1.3. Appointments of Provincial Government Analyst under Section 16 of the Drugs Act, 1976.

13.1.4. Appointments of Provincial inspectors of drugs under Section 17 of the Drugs Act, 1976 on the recommendations of the Authority.

13.1.5. Establishment of Drug Testing Laboratories for testing and research purposes.

13.1.6. Establishment of Provincial Quality Control Boards (PQCBs) for following functions:

13.1.6.1. To inspect any premises where any drug is being or is to be, manufactured or sold;

13.1.6.2. To recommend to the appropriate authority to cancel / suspend a license to manufacture or sell drugs;

13.1.6.3. To scrutinize the reports of provincial inspectors and provincial government analyst and issue instructions to the inspectors for the actions to be taken on such reports;

13.1.6.4. To specify cases in which a provincial inspector may make a complaint to the Drug Courts or take any other action;

13.1.6.5. To exercise all the powers of an Inspector under this Act and the rules;

13.1.6.6. To advise the Provincial Government on ways and means to ensure quality control of drugs manufactured in the Province;

13.1.6.7. To ascertain the names of such directors, partners and employees of the company, corporation, firm or institution who are prima facie responsible for the commission of any offence under this Act or the rules and allow an Inspector to institute prosecution only against such person;

13.1.6.8. To conduct annual validation of all instruments in the provincial drug testing laboratories and to recommend measures to upgrade such laboratories, if required;

13.1.6.9. Identify and accredit on payment of fee other laboratories in the Province with suitable facilities and expertise;

13.1.6.10. To conduct training programs to update Government Analysts and for improving their knowledge according to latest analytical method and technology; and

13.1.6.11. To submit a monthly report of decisions and activities to the Federal Government.

13.1.6.12. Delegation of any power to any of its members for smooth execution of tasks.

13.1.7. Communication between DRAP and Provincial Governments is in the form of official communication means i.e. through letters to:

13.1.7.1. Chief Executive Officer;

13.1.7.2. Secretary of the relevant Board or Committee;

13.1.7.3. Concerned Division.

14. REFERENCES

14.1. Drugs Act, 1976

14.2. DRAP Act, 2012

14.3. Rules framed thereunder.

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