[AS INTRODUCED IN THE SENATE]

A

BILL

to provide for the establishment of Drug Regulatory Authority of Pakistan

WHEREAS the Drug Regulatory Authority shall address all components of drugs manufacturing and its sales and distribution; and its Board shall consist of members who are from the healthcare field and have reasonable educational background to oversee the assigned tasks. The Board shall operate with independence and autonomy and shall not be interfered by political or bureaucratic influences;

AND WHEREAS it is expedient to establish a Drug Regulatory Authority of Pakistan to regulate, enforce and monitor all facets pertinent to provision of affordable and quality medicines to the nation;

AND WHEREAS to provide for effective coordination and enforcement of Drugs Act for therapeutic goods relating to their production, use and import into and export from Pakistan; to bring harmony in inter-provincial trade and commerce of therapeutic goods; to improve access to drugs by establishing and enforcing standards of quality of therapeutic goods sold and exported out of Pakistan through regulation of all aspects related to therapeutic goods including their manufacturing, registration, pricing, safety, efficacy, quality, need, specifications, access and economic value;

AND WHEREAS to regulate the complete Supply Chain of sale of Therapeutic goods through the Chemists, Dispensaries, wholesale and distributors and ensure their storage, quality and safety standards, and strict enforcement of warranty and invoice at all levels;

AND WHEREAS to regulate the production, import, export, use and sale of Biological and Medical devices and instruments;

CHAPTER I
PRELIMINARY

1. Short title, extent and commencement.– (1) This Act may be called the Drug Regulatory Authority of Pakistan Act, 2012.

(2) It extends to the whole of Pakistan.

(3) It shall come into force at once.

2. Definitions.– In this Act, unless there is anything repugnant in the subject or context,-

(i) Authority" means the Drug Regulatory Authority of Pakistan established under section 3;

(ii) "Board" means the Board of Drug Regulatory Authority of Pakistan constituted under section 9;

(iii) “CEO” means the Chief Executive Officer of the Authority appointed under section 5;

(iv) “Chairman” means the Chairman of the Board;

(v) Civil Servant means a civil servant as defined in the Civil Servants Act, 1973 (LXXI OF 1973);

(vi) “decision” includes an order, determination or direction of the Authority or the Board made in accordance with laws, rules and regulations;

(vii) “Drug” as defined in Drugs Act, 1976;

(viii) “fee” as prescribed by the Board for any service;

(ix) “Federal Government” means the Prime Minister of Pakistan;

(x) “Fund” means the Drug Regulatory Authority of Pakistan Fund established under section 19;

(xi) “Inspectors” the Federal Government or a Provincial Government may, by notification in the official Gazette, appoint such persons as it thinks fit, having the prescribed qualifications, to be Federal Inspectors, or, as the case may be, Provincial Inspectors for the purposes of this Act within such local limits as it may assign to them respectively;

(xii) “Medical device” includes,-

(i) instruments, medical equipment, implants, disposables and software, used mainly for the purpose of diagnosis, monitoring and treatment of disease; or

(ii) any other item which the Federal Government may, by notification in the official Gazette, declare as medical device;

(xiii) “Medicine” means alternatives medicine other than the drug and includes homoeopathic and traditional medicines such as unani, ayurvedic and biochemical medicines;

(xiv) “Member” means a Member of the Board;

(xv) “Therapeutic goods” includes drug or medicine or medical device or biological or as may be notified by the Authority;

(xvi) “Penalty” as prescribed, or may be prescribed, through an Act of Parliament;

(xvii) “person” means any individual or any legal entity;

(xviii) “Pharmaceutical field” means regulation, manufacturing, quality control, import, export and pharmacy services in drugs;

(xix) “Pharmacy Services” means services rendered by pharmacist in pharmaceutical care, selection, posology, counseling, dispensing, use, administration, prescription monitoring, pharma-c0oepidemiology, therapeutic goods information and poison control, pharma-covigillance, pharma-coeconomics, distributions, storage, sales, procurement, forecasting, supply chain management, drug utilization evaluation, drug utilization review, formulary based drug utilization and managing therapeutic goods at all levels including pharmacy, clinic, medical store, hospital or medical institution;

(xx) “prescribed” means prescribed by rules or regulations through an Act of Parliament;

(xxi) “prohibitions” as defined, or may be defined, through an Act of Parliament;

(xxii) “Regulation” means the regulations made under this Act;

(xxiii) “Rules” means the rules made under this Act;

(xxiii) “Secretary” means Secretary of the Board; and

(xxiv) “Schedule” means schedules of the relevant Acts of Parliament.

CHAPTER II
AUTHORITY AND BOARD

3. Establishment of the Authority.– (1) As soon as may be, after the approval of this Act, the Federal Government shall establish an Authority to be known as the Drug Regulatory Authority of Pakistan to carry out the purposes of this Act which shall work under the Board of Drug Regulatory Authority.

(2) The Authority shall be a body corporate having perpetual succession and a common seal with powers, subject to the provisions of this Act, to acquire, purchase, hold and dispose of property both movable and immovable and shall by its name sue and be sued.

(3) The Authority shall be an autonomous body working under the Prime Minister of Pakistan.

(4) The Headquarters of the Authority shall be at Islamabad.

(5) The Authority may set up its establishments including its offices and sub-offices at Provincial Capitals and such other places, as it may deem necessary from time to time. Some of the existing Federal Drugs Control Administration and the sub-offices set up in all Provinces and laboratories called the Central Drugs Laboratory, Karachi, the National Control Laboratory for Biological, Islamabad and the Surveillance Laboratory, Islamabad shall, upon the approval of this Act, become part of the Authority, subject to sub-section (2) of section 14.

4. Composition of the Authority:– (1) The Authority shall consist of a Chief Executive Officer and nine (9) full time Members all of whom shall be appointed by the Board.

(2) The qualifications and terms and conditions of appointment for members shall be such as may be prescribed. The members shall be designated as,-

(i) Member Pharma Licencing;
(ii) Member Drug Registration;
(iii) Member Drug Testing Laboratory;
(iv) Member Pharma Quality Assurance;
(v) Member Pharmacy Services;
(vi) Member Biological and Medical Devices;
(vii) Member Alternative/Traditional Medicines and Nutritional Products (Ayurvedic, Unani and Homeopathy);
(viii) Member Costing and Pricing; and
(ix) Member Administration, Human Resources and Legal Affairs.

(3) The Federal Government, on the recommendations of the Board, may increase or decrease the number of Members and prescribe the qualifications, terms, mode and manner of their appointment.

5. Chief Executive Officer.– (1) The Board may appoint a person as Chief Executive Officer (CEO) who has M Phil/PhD degree in any discipline of pharmacy with a minimum of twenty years experience, in the field of healthcare from either public or private sector.

(2) The Chief Executive Officer (CEO) shall be the head of the Authority and shall discharge such duties and perform such functions as are assigned to him by or under this Act or as may be prescribed by the Board.

6. Meetings of the Authority.– (1) Save as hereinafter provided, the Authority shall regulate the procedure for its meetings.

(2) The meetings of the Authority shall be convened by and under the directions of the Chief Executive Officer (CEO) at any time on any matter requiring decision by the Authority.

7. Powers and functions of the Authority.– The powers and functions of the Authority shall be to,-

(i) administer the laws specified in the relevant Acts of Parliament and Rules framed thereunder that apply to Federal Government, and advise the Provincial Governments for the laws that are applicable to the provinces;

(ii) monitor the enforcement of laws specified in the relevant Acts of Parliament and collect relevant data and information;

(iii) subject to approval of the Board, issue guidelines and monitor enforcement of,-

(a) licensing of therapeutic goods;

(b) registration of therapeutic goods;

(c) specifications and laboratory practices;

(d) determining standards for biological manufacturing and testing;

(e) regulation for pricing and mechanism for fixation of prices of various Healthcare services under its ambit;

(f) implementation of internationally recognized standards such as Good Laboratory Practices (GLP), Good Manufacturing Practices (GMP) etc.;

(g) regulation and allocation of quota of narcotics and psychotropic drugs and precursor substances;

(h) inspections, investigations and other like functions;

(i) prosecution and appeals under this Bill relating to federal subjects;

(j) regulation, enforcement and monitoring of advertising rule and ban on false advertisements; and

(k) any other function under this Bill which the Authority may deem fit.

(iv) coordinate, monitor or engage, in conjunction with other organizations, Provincial Governments and international agencies, in training, study or project related to healthcare. 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;

(v) facilitate advancement and upgradation of healthcare sector to meet international standards and also to promote export of therapeutic goods;

(vi) coordinate at policy level and provide policy guidance to the Provincial Governments in the performance of their functions with a purpose to bring uniformity;

(vii) facilitate the procurement and implementation of foreign aided technical assistance on healthcare where such expertise does not exist but its existence would promote public health and well being;

(viii) take steps for development and promotion of healthcare services;

(ix) undertake awareness campaigns regarding prevention of diseases, patients rights, healthcare privileges etc. through media, seminars, publications and other available means;

(x) issue guidelines and monitor proceedings and their funding and accounts of health seminars, workshops and conferences;

(xi) appoint such employees, consultants and experts as deemed necessary on such terms and conditions including their salaries and remunerations on consultation and approval of the Board. Such recruitment, continuation and remuneration to be based on merit and productivity;

(xii) prescribe rules for seniority, promotion, code of conduct of its employees;

(xiii) levy such charges or fees as may be prescribed for services and facilities provided by the Authority and its offices;

(xiv) carry out such other works or activities as may be deemed necessary by the Authority to carry out the purposes of this Bill;

(xv) 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;

(xvi) prepare annual budget to be approved by the Board;

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

(xviii) develop working manuals, guidelines, references, materials and procedures in order to improve the working environment of offices etc. set up under the Authority;

(xix) prescribe, regulate or implement measures and standards on matters related or connected with the Authority; and

(xx) perform and carry out any other act, duty or function as may be assigned to it by the Federal Government.

8. Delegation of Powers.– The Authority may, by general or special order in writing subject to such condition or limitations, delegate any of its powers and function to any officer as it may deem appropriate.

9. Board of the Drug Regulatory Authority of Pakistan.– (1) There shall be a Board of the Drug Regulatory Authority of Pakistan consisting of the following, namely:-

(i)	A person to be appointed by Prime Minister having credible qualification and experience in the healthcare sector.	Chairman
(ii)	Secretary (Grade 22 to be appointed by Prime Minister having reasonable healthcare experience.	Member
(iii)	Chief Executive Officer (CEO) of Drug Regulatory Authority (DRA) to be appointed by the Board.	Member
(iv)	five Health Secretaries (one from each Province and Gilgit Baltistan)	Member
(v)	one representative each from Islamabad Capital Territory and FATA from the Government's Health Administration.	Member
(vi)	three expert members who are owners/MDs of Pharma Industry (from Top fifty companies as per Audited balance sheets) to be nominated by their respective Associations, one each from Pharma Bureau (PB), Pakistan Pharmaceutical Manufacturer Association (PPMA) and Association of Pharmaceutical Exporters of Pakistan (APEX).	Member
(vii)	six expert out of which three expert members who are Professors Doctor of Medicine (one each from Private, Public and Army Hospital) + three experts of Toxicology, Infectious Diseases and Epidemic Control, five of whom from the public and private to be nominated by College of Physicians and Surgeons of Pakistan (CPSP) and one Professor of Army Hospital to be nominated by Army General Head Quarter (GHQ) Military Secretary Branch.	Member
(viii)	One expert member from Clinical Pharmacy Services to be nominated by Pakistan Pharmacist Association (PPA) and one expert members from Community Pharmacy Services to be nominated from Pakistan Chemists and Druggist Association (PCDA).	Member

(2) The Board shall look after the Drug Regulatory Authority (DRA) through the Chief Executive Officer CEO:

Provided that in the event of vacancy in the office of the Chairman of the Board by reason of his death, resignation, removal or otherwise, the Board shall elect an Acting Chairman from amongst themselves through a majority vote. The Acting Chairman shall hold office until the appointment of a new Chairman by the Federal Government to fill such vacancy which shall not exceed ninety (90) days:

Provided further each term of the expert member of the Board shall be for a period of three years. Provided further, that the expert member shall be appointed, and can be re-appointed, subject to approval of the Board:

Provided further that no representative of the expert Member, through proxy or verbal are written authorization, shall be permitted on the Board.

(3) And, notwithstanding the composition of the Board constituted under sub-section (1) and (2), the Board may increase or decrease the number of its members and prescribe the qualifications and procedure for their appointment/selection through a two-third (2/3rd) majority of votes, ensuring majority of private expert members.

10. Meeting of the Board.– (1) Save as hereinafter provided, the Board shall make regulations for the conduct of its business.

(2) The meetings of the Board shall be convened by the Secretary of the Board with the prior approval of the Chairman and in case of absence of the Chairman the members present can elect the Chairman for the meeting.

(3) The meetings of the Board shall be held at least once a month. A special meeting may also be called at any time to deal with any urgent business.

(4) A simple majority of the total membership shall constitute the quorum for a meeting of the Board and in case of equality of votes, the Chairman or the person presiding over the meeting shall have a casting vote.

(5) All decisions, determinations taken by the Board shall be taken in writing.

(6) The Board meeting shall be called by giving an advance notice of at least seven days.

11. Functions of the Board.– (1) The Board shall have the following functions, namely:-

(i) to frame the drugs regulatory policies, provide guidelines and monitor the implementation and performance of the guidelines and of the functions of the Authority;

(ii) approval of the Budget of the Authority;

(iii) determine the fees;

(iv) appoint Chief Executive Officer (CEO) of the Authority as per sub-section (i) of section 5 and any other additional terms, conditions, expertise and experience, the Board feels would benefit in the execution of the functions of the Authority; and

(v) appoint members of the Authority, in consultation with the Chief Executive Officer (CEO) on such terms and conditions including but not limited to their salaries and allowances.

(2) The Federal Government, as and when it considers necessary, may issue policy directives in accordance with law to the Authority, in respect of its activities and the compliance whereof shall be binding on the Authority, within a stipulated time.

(3) Notwithstanding anything contained in sub-section (2), if there is any difficulty in implementation of the directions and guidelines of the Board, the Authority, with reasons for non-implementation, within the stipulated time, refer the case back to the Board for its review.

12. Committees of the Board.– (1) The Board may constitute committees of experts as it considers necessary or expedient to assist it in the performance of its functions under this Bill.

(2) A committee constituted under sub-section (1) shall act in accordance with the regulations made by the Board.

13. Board may invite others to meeting.– The Board may invite any person to attend its any meeting or deliberations including any meeting of the committees for the purpose of advising it on any matter under discussion but such person shall have no right to vote at the meeting or deliberation.

14. Appointment of officers and employees etc. of the Authority.– (1) The Authority with approval of the Board, may create posts and appoint such officers, employees, experts and consultants, as it may consider necessary for the performance of its functions.

(2) Selection, recruitment, appointment of all officers, employees, experts and consultants including the officers/employees of the Federal Drug Control Administration, the sub-offices or laboratories as referred in sub-section (v) of section 3 shall be based on merit. The criteria for recruitment/selection of employees/officers shall be determined by the Board according to the prescribed rules.

(3) Any officer or employee of the Federal Drug Control Administration, the sub-offices or laboratories as referred to in sub-section (5) of section 3, if recruited, shall have the option either to remain a civil servant or be an employee of the Authority. The option once exercised shall be final.

(4) An officer or employee as referred to in sub-section (3), on giving option to be an employee of the Authority, be deemed to have been appointed or engaged by the Authority in accordance with the terms and conditions which shall not be varied to their disadvantage. The age of superannuation for each member, shall be sixty years.

15. Integration of Federal Drugs Control Administration its sub-offices and Laboratories.– Upon the approval the Bill, some of the employees of the Drugs Control Administration, its sub-offices, its Laboratories hereinafter referred to as the said offices shall become part of the Authority; and

(i) all assets, rights, powers, authorities and privileges and all properties, movable and immovable, cash and bank balance, reserve funds, investment and all other interest and rights in, or arising out of such properties and all debts, liabilities and obligations of whatever kind of the said offices subsisting immediately before their integration shall stand transferred to and vest in the Authority;

(ii) all debts and obligations incurred or contracts entered into or rights acquire and all matters and things engaged to be done by, with or for the said offices before their integration, shall be deemed to have been incurred, entered into, acquired or engaged to be done by or for the Authority; and

(iii) all suits and other legal proceedings instituted by or against the said offices before their integration shall be deemed to be suits and proceedings by or against the Authority and may be proceeded or otherwise dealt with accordingly.

16. Experts, consultants and advisers not to be civil servants.– The experts consultants or advisers employed by the Authority shall be governed by the terms and conditions of their appointment and shall not be deemed to be civil servant within the meaning of the Civil Servants Act, 1973 (LXX1 of 1973).

17. Chief Executive Officer (CEO) and officers etc. to be public servant.– The Chief Executive Officer CEO, officers, employees, experts and consultants of the Authority shall, when acting or purporting to act in pursuance of any of the provisions of the Act, be deemed to be public servants within the meaning of section 21 of the Pakistan Penal Code (Act XLV of 1860).

18. Conflict of interest.– No person shall be appointed as CEO, member, consultant, advisor, officer or employee of the Authority if he/she has any financial or professional conflict of interest.

CHAPTER III
FUND, BUDGET AND ACCOUNTS

19. Drug Regulatory Authority Fund.– (1) There shall be a fund to be known as the Drug Regulatory Authority of Pakistan Fund which shall vest in the Authority and shall be utilized by the Authority to meet its expenses and charges properly incurred in connection with the carrying out of its functions and duties assigned or transferred to it under this Bill, including but not limited to the payment of salaries and other remuneration to the CEO, members, employees, experts, consultants and advisers of the Authority.

(2) The Drug Regulatory Authority Fund shall be financed from the following sources, namely:-

(i) initial Grant to be provided by the Federal Government;

(ii) grants and loans by the Federal Government and Provincial Governments;

(iii) loans and grants from the national and international agencies received by the Federal and Provincial Governments or the Authority to finance the functions of the Authority;

(iv) charges and fees collected by the Authority to recover the costs of regulated activities under this Bill;

(v) proceeds of any investments made by the Authority which are not required for immediate use. All investments to be made by the Authority shall be with the approval of the Board; and

(vi) proceeds from any other service rendered by the Authority, including Inspection Services, foreign or local, or sale of any publication, or workshops/symposias/seminars etc.

20. Fees and other charges to be levied by the Authority.– The Authority shall levy and collect such fees and fines in respect of any of its functions at such rates as may be determined from time to time by the Authority, with the approval of the Board, in accordance with rules.

21. Budget.– (1) The Authority shall, in respect of each financial year prepare on such date as may be prescribed, a statement of the estimated receipts and expenditures, including the budgets and requirements of foreign exchange for the next financial year for consideration and approval of the Board. Any foreign exchange requirements within the overall annual approved budget by the board shall be sent to Ministry of Finance in the Federal Government for appropriate provision and allocation.

(2) It shall not be necessary for the Authority to take prior approval from the Government to spend money from its funds, and the Authority shall practice financial freedom as the Board deems fit for furtherance of its functions.

22. Accounts and Audit.– (1) The Authority may open its accounts with any scheduled bank(s) or financial institution(s) within the framework of the regulation prescribed in this regard by the Federal Government, with the initial grant by the Federal Government, in the amount, as may be determined by the Federal Government.

(2) The accounts of the Authority shall be maintained in the manner prescribed by the Controller General of Accounts.

(3) The Authority shall cause to be carried out audit of its accounts by one or more auditors registered as chartered accountants within the meaning of the Chartered Accountants Ordinance; 1961 (X of 1961).

(4) Notwithstanding the audit provided by in sub-section (3), the Auditor General shall have the power to audit or cause to be audited the accounts of the Authority.

(5) A copy of the audit report shall be sent to the Federal Government along with the comments of the Authority.

(6) The Authority may take such steps for the rectification of any objection raised by the Auditor-General of Pakistan.

CHAPTER IV
RULES AND REGULATIONS

23. Power to make rules.– The Authority may, by notification in the official Gazette, with the approval of the Board and the Federal Government, make rules for carrying out purposes of this Act:

Provided that where it is necessary to issue notification under Scheduled laws and the amendment in rules is required for day-to-day business, the Authority may notify such amendment with approval of the Board.

24. Power to make regulations.– The Authority may, by notification in the official Gazette, with the approval of the Board, make regulations, not inconsistent with the provisions of the Bill or the rules, for the carrying out of its functions under this Bill.

CHAPTER V
MISCELLANEOUS

25. Submission of annual reports and returns.– (1) Within three months of the conclusion of each financial year, the Authority shall submit an annual report to the Federal Government in respect of the activities of the Authority including the status of its existing programmes, projects and further plans formulated in furtherance of its functions.

(2) The Federal Government may require the Authority to furnish,-

(i) any return, statement, estimate, statistics or other information regarding any matter under the control of the Authority;

(ii) a report on any subject related to the Authority; and

(iii) a copy of any document in the custody of the Authority.

(3) The Authority shall expeditiously comply with such directions.

26. Power to call for information.– The Authority may call for any person, involved directly or indirectly and reasonably believed to having such information in his control or possession which is required for carrying out the purposes of this Bill. The person so called upon to provide such information shall do so within the period prescribed by the Authority and in case of failure to do so he shall be punished by imposition of such penalty which may not exceed one hundred thousand rupees or as may be prescribed.

27. Offences by companies etc.– Where the person guilty of an offence under this Act, is a company, corporation, firm or institution, every director, partner and employee of the company, corporation, firm or institution (with whose knowledge or consent the offence was committed) shall be guilty to the offence.

28. Cognizance of offences.– The procedures and Penalties applicable to the inspectors/officers/employees of the Authority in case of their cognizance of offence shall be such as prescribed, or may be prescribed, under an Act of Parliament.

29. Complaints.– (1) Any aggrieved person may file a written complaint with the Authority against contravention of any provision of this Act or any other law against an employee of the Authority.

(2) The Authority shall, on receipt of a complaint cause it to be investigated as may be prescribed and provide an opportunity to the complainant as well as the employee against whom such complaints has been made. The Authority may, on completion of investigation, take any action as may be prescribed under this Bill or as the case may be subject to the provisions of the law.

(3) Appeals against the decisions of the Authority shall be referred to the Board, which shall formulate an Appellate Committee from among its members, through a simple majority vote.

30. Existing agreement.– If on the approval of this Bill there exists an agreement in respect of, or dealing with, a regulated activity to which the Federal Government is a party, in the event of any inconsistency between the provisions of this Bill, the rules or the regulations, the provisions of the agreement shall prevail to the extent of the inconsistency.

31. Confidential Information.– (1) Except as provided under the regulations, no person shall communicate, or allow to be communicated, any record or information obtained under this Bill to a person not legally entitled to that record or information or allows any person not legally entitled to that record or information to have access to any record obtained under this Bill.

(2) A person who knowingly receives records or information obtained under this Bill shall hold the record or information subject to the same restrictions under sub-section (i) as apply to the person from whom the records or information were received.

32. Act not in derogation of the Drug Act 1976.– The provisions of this Act shall be in addition to, and not in derogation of, the Drugs Act, 1976 (XXXI of 1976).

33. Act to prevail any other law:– Other than Drug Act 1976, any other law for the time being enforced, the provision of this Act shall prevail.

34. Recovery of arrears.– All amounts due to the Authority may be recovered as arrears of land revenue.

35. Indemnity.– No suit, prosecution or other legal proceeding shall lie against any person for anything which is in good faith done or intended to be done under this Bill or any rules or regulations made there-under.

36. Winding up of the Authority.– No provision of any law relating to winding up of bodies corporate shall apply to the Authority. The Authority shall only be wound up by the law to be enacted by Parliament for winding up of the Authority.

37. Power to amend Schedule.– The Federal Government may amend the Schedule so as to add any entry thereto or modify or omit any entry there-from.

38. Removal of difficulties.– If any difficulty arises in giving effect to any of the provisions of this Act, the Federal Government may make such Order by notification in the official Gazette, not inconsistent with the provisions of the Act, for the purpose of removing the difficulty.

STATEMENT OF OBJECTS AND REASONS

1. The Bill is aimed in the establishment of the Drug Regulatory Authority of Pakistan in order to address all components of drugs manufacturing and its sales and distribution and to constitute a Board consisting of members who are from the healthcare field and have reasonable educational background to oversee the assigned tasks. The Board shall operate with independence and autonomy and shall not be interfered by political or bureaucratic influences.

2. The Drug Regulatory Authority of Pakistan will regulate, enforce and monitor all facets pertinent to provision of affordable and quality medicines to the nation.

3. The proposed Act will provide effective coordination and enforcement of Law for therapeutic goods relating to their production, use and import into and export from Pakistan and will bring harmony in inter-provincial trade and commerce of therapeutic goods. It will improve access to drugs by establishing and enforcing standards of quality of therapeutic goods sold and exported out of Pakistan through regulation of all aspects related to therapeutic goods including their manufacturing, registration, pricing, safety, efficacy, quality, need, specifications, access and economic value.

4. It is also aimed to regulate the complete supply chain of sale of Therapeutic goods through the Chemists, Dispensaries, wholesale and distributors and ensure their storage, quality and safety standards, and strict enforcement of warranty and invoice at all levels. It will also regulate the production, import, export, use and sale of Biological and Medical devices and instruments.

5. The Bill is designed to achieve the aforesaid objects.

SENATOR ABDUL HASEEB KHAN
Member-in-Charge