24. Registration Board: (1) The Registration Board shall consist of such members, including the Chairman and the Secretary, and its members shall hold office for such term, as is prescribed for the Central Licensing Board set up under rule 8.

(2) The Registration Board may refer any case for detailed examination to the committee of experts on the Drugs Evaluation constituted under Section 10 of the Act.

(3) The Registration Board may appoint a sub-committee consisting of at least one Clinical Professor, one pharmacologist and one pharmacist to make a detailed examination of each case and to submit a report for the consideration of the Board.

(4) The Registration Board may appoint a panel of experts or inspectors to inspect on behalf of the Board the premises of a manufacturer of drugs and to submit its report to the Board.

(5) The Chairman and the Secretary of the Registration Board shall, after the Board has approved the registration of a drug, sign the certificate of registration.

(6) For the manner and conduct of the meetings of the Registration Board, the provisions of sub-rules (3), (4), (5), (6), (7), (8), and (9) of rule 8 shall mutatis mutandis apply.
25. **Powers of Registration Board:** The members of the Registration Board shall exercise all the powers of Inspector without restriction as the area, and shall have the powers of a Provincial Inspector in relation to Section 30.

26. **Application for registration of drugs and fees thereof:** (1) An application for registration of a drug shall be made in Form 5 or 5-A in duplicate to the Registration Board addressed to its Secretary, and separate application shall be made for each drug.

(2) The applicant shall furnish such further information and material as may be required by the Registration Board for the proper evaluation of the drug.

(3) An application under sub-rule (1) shall be accompanied by fee or-

(a) rupees one thousand for the registration of new drug;

(b) rupees five hundred for the registration of any other drug; and

(c) rupees two hundred and fifty for the renewal of the registration of a new or any other drug:

Provided that the application for the renewal of registration is made before the expiry of the validity of the certificate of registration.

(3-A) Application for renewal of registration of a drug shall be made in Form 5-B.

(3-B) Any application under sub-rule (1) or sub-rule (3) shall be accompanied by the proper fee specified in Schedule F.

(4) If the application for renewal of registration is made after the expiry of the period of the validity of the certificate or registration, it shall be treated as a fresh application for the registration of drug.

(5) A fee of rupees fifty shall be paid for a duplicate copy of the certificate of registration if the original is defaced, damaged or lost, and such copy of the certificate shall bear the words "Duplicate Copy".

(6) Any fee deposited under sub-rule (3) shall in no case be refunded.
27. **Duration of certificate of registration:** A certificate of registration under this chapter, shall, unless earlier suspended or cancelled, be in force for a period of five years from the date of Registration of the drug and may thereafter be renewed for periods not exceeding 5 years at a time.

Provided that an application for the renewal of registration shall not be entertained unless it has been made within sixty days after the expiry of the registration and when an application has been made as aforesaid the registration shall subject to the orders passed on the application for the renewal continue in force for the next period of five years:

Provided further that, if in the opinion of the Registration Board it is necessary so to do in the Public interest, it may provisionally register a [...] drug for period of two years.

28. **Certificate of registration:** A certificate of registration of drug shall be issued in Form 6.

29. **Procedure for registration:** (1) The Registration Board may, if it considers necessary, cause the application for registration and the information and material supplied to it under rule 26 to be evaluated by a Committee on Drugs Evaluation consisting of experts related to the aspect of the drug to be evaluated and obtain its report.

(2) The Registration Board may, before issuing a registration], cause the premises in which the manufacture is proposed to be conducted to be inspected by itself or by its sub-committee or by a panel of Inspectors or experts appointed by it for the purpose, which may examine all portions of the premises and the plant and appliances, inspect the process of manufacture intended to be employed and the means to be employed for standardising, if necessary, and testing the substances to be manufactured and enquire into the professional qualifications of the technical staff employed.
(3) Where inspection under sub-rule (2) is carried out by a Sub-Committee or panel of experts or Inspectors appointed under the said sub-rule, it shall forward to the Registration Board a detailed report of the result of the inspection.

(4) If the Registration Board, after such further enquiry, if any, as it may consider necessary, is satisfied of its safety, efficacy, quality and economical value or where the public interest so requires, it may register the drug and issue a certificate of registration in Form 6, subject to such specific conditions as it may specify.

(5) The Registration Board may, while registering a drug under sub-rule (4), approve the details as supplied by the applicant or approve them with amendments as it may deem fit in respect of the following particulars, namely:

(a) the name under which the drug may be sold;
(b) the labelling;
(c) the statement of all the representations to be made for the promotion of the drug in respect of:
   (i) the claims to be made for the drug;
   (ii) the route of administration;
   (iii) the dosage;
   (iv) the contra-indications, the side effects and precautions if any; and

(d) Omitted by S.R.O. 551(1)//93, dated 3. 7. 1993.

(5-A) Where the Registration Board registers a new drug, it may recommend to the Federal Government for fixation of maximum price of such drug.
(6) The Registration Board shall, before registering a new drug for which the research work has been conducted in other countries and its efficacy, safety and quality has been established therein, require the investigation on such pharmaceutical, pharmacological and other aspects, to be conducted and clinical trials to be made as are necessary to establish its quality and, where applicable, the biological, availability, and its safety and efficacy to be established under the local conditions:

Provided that under special circumstances to be recorded in writing, the Registration Board may register a drug and require such investigations and clinical trials to be conducted after its registration.

(7) A new drug, where new method of manufacture is contemplated or a change is proposed in source, standard or specification of the active ingredient or the finished product, may not require full investigations and clinical trials except in so far as they are necessary for the purpose of establishing bio-equivalence, absorption, acceptability or other such features.

(8) Where it is necessary in the public interest so to do, the Registration Board may register a drug on its own motion without having received any application for registration.

(9) If the Registration Board is not satisfied as to the safety, efficacy, quality or economic value of a drug, or where the public interest so requires it may, [ . . . ]..., reject the application for registration and inform the applicant of the reasons for such rejection in writing.

(10) Rejection of an application for the registration of a drug shall not debar an applicant from submitting a fresh application under rule 26.

30. Conditions or registration of drug: (1) The relevant provisions of the Ordinance and the rules in respect of the registered drug, shall be complied with.
(2) The import, manufacture and sale of drugs shall be in accordance with the information contained in the applications in respect of those drugs or in any supplementary information or, where such information was amended by the Registration Board, in accordance with such amended information on the basis of which such drugs were registered:

Provided that deviations from any such information may be made only after obtaining prior approval of the Registration Board.

(3) The indications, contra-indication, side effects, the dosage and cautions, if any, as have been approved for the purpose of registration of a drug shall be clearly specified in the labelling and promotion.

(4) Every drug shall be produced in sufficient quantity so as to ensure its regular and adequate supply in the market.

(5) The manufacture of any drug shall not, without the prior approval of the Registration Board, be discontinued for period which may result in its shortage:

Provided that in the circumstances beyond the control of a manufacturer, of a drug which may lead to reduction in the production of that drug, the circumstances may be intimated to the Registration Board.

(6) A record of quarterly production and disposal of a drug shall be maintained and supplied to the Chairman of the Registration Board in Form 7 in the months of January, April, July and October each year.
(7) In case of an imported drug, the indenter or any other approved representative in Pakistan of the foreign firm shall ensure regular and adequate supply of the drug in Pakistan.

(7-A) The indenter, importer or manufacturer's authorised agent shall issue a warranty in Form 2-A for any drug indented or sold by him for the purpose of resale or distribution; and

(8) In respect of new drug, records, including adequately organised and indexed files, shall be maintained containing full information regarding--

(a) animal or clinical investigations and tests conducted by the manufacturer or reported to him by any person concerning that drug;

(b) reports from the scientific literature or the bibliography therefrom that are available to him concerning that drug;

(c) experiences, investigations, studies and tests involving the chemical or physical properties or any other properties of that drug;

(d) any substitution of another substance for that drug or any mixing of another substance with that drug;

(e) any error in the labelling of that drug;

(f) any bacteriological or any significant chemical or physical or other change or deterioration in any batch of that drug;

(g) any failure of one or more distributed batches of that drug to meet the required specifications;

(h) any unexpected side effects, injury, toxicity or sensitivity reaction associated with the clinical uses, studies, investigations and tests respecting that drug; and

(i) any unusual failure of that drug to produce its expected pharmacological activity.
(9) The following information shall be supplied to the Registration Board—

(a) on request, report in duplicate of all records respecting the information contemplated by paragraphs (d), (e), and (f) of sub-rule (8); and

(b) immediately upon receipt by him, reports in duplicate of all records respecting the information contemplated by paragraphs (d), (e) and (f) of sub-rule (8); and

(c) as soon as possible and in any event within fifteen working days of their receipt by him, reports in duplicate of all records respecting the information contemplated by paragraphs (g), (h) and (i) of sub-rule (8).

(10) If a drug or any of its ingredients, which is imported or manufactured by a company in Pakistan is also approved for registration and free sale by its subsidiary, sister concern, associate or parent company in the country where it was originally developed or in any of the countries namely, USA, European Union Countries, Canada, Japan, Australia, and--

(a) if that drug at any time, for safety reasons is withdrawn or banned or certain restrictions are imposed in any of the said countries, then it shall be the responsibility of the manufacturer in Pakistan or as the case may be, the indentor, to immediately withdraw the drug from the market in Pakistan or, as the case may be to impose similar restriction and to inform the registration Board within fourteen days of such an information having come to his knowledge and having taken the necessary action. The Registration Board after getting the said intimation shall take similar action for the same drug available from other sources within the shortest possible time;

(b) if a climical information for a drug is approved by the Drug Regulatory Authority in any of the said countries, the same clinical information shall be considered as approved for drug registration in Pakistan unless modified by the Registration Board on the basis of scientific data available to it, and such clinical information may include indication, contra-indications, side effects, precautions, dosage, etc;
(c) if any adverse drug reaction not otherwise included in the application for registration, is registered in any of the said countries, it shall be the responsibility of the concerned manufacturer or in case of imported drugs the indentor or manufacturer’s agent in Pakistan, to be aware of such adverse action and to report to the Registration Board within thirty days of becoming so aware.

(11) The manufacturer or as the case may be, the indentor shall follow the ethical criteria for medical drug promotion as given in Schedule G.

(12) The manufacturer or, as the case may be, the indentor shall supply the information in relation to safety, efficacy, production, quality, or availability of the drugs as and when required by the Registration Board with a view to ensure safety, efficacy or quality of the drug.