GOVERNMENT OF KHYBER PAKHTUNKHWA HEALTH AND SOCIAL WELFARE DEPARTMENT
NOTIFICATION.

31st May, 1982.

No. SOH(III)Tech DC.1-I/79. — In exercise of the powers conferred by section 44 of Drugs Act, 1976 (XXXI of 1976), the Government of N.-W.F.P. is pleased to make the following Drugs Rules namely The N.-W.F.P. Drugs Rules. 1982.

PART-I

PRELIMINARY.—

1. Short title and commencement—(1) These rules may be called the North-West Frontier Province Drugs Rules, 1982.
(2) They shall come into force at once.

2. Definitions.—In these rules unless there is anything repugnant in the subject or context
   (a) “Act” means the Drugs Act, 1976 (XXXI of 1976);
   (b) “Analyst” means an Analyst appointed by Government under the Act;
   (c) “Board” means the Quality Control Board for the North-West Frontier Province, set up under section 11;
   (d) “Form” means a form specified in Schedule A
   (e) “Government” means the Government of the Khyber Pakhtunkhwa province;
   (f) “Inspector” means an Inspector appointed by Government under the Act;
   (g) “Licensing authority” means the authority specified in rule 12;
   (h) “Narcotics” means the drugs specified in Schedule B;
   (i) “Pharmacy” means a shop, store or a place where drugs are compounded or prepared on prescriptions.
      “Schedule” means a schedule to these rules; and
   (j) “Section” means a Section of the Act.

PART-II

APPOINTMENT AND FUNCTION OF ENFORCEMENT STAFF

3. Procedure in case of prosecution—(1) — An inspector and an Analyst shall submit monthly returns in Form 1 and Form 2, respectively, to the Board and a summary on the overall situation of quality control in the area under their respective jurisdiction and the Board shall maintain such information in a manner so as to monitor the quality of all the drugs sold and to keep watch on the performance of all manufactures.
(2) The Board shall, as far as possible, meet at least once in a month and review the situation of the quality control of drugs on the whole including consideration of any specific point arising during the period on the working of the various firms, Drug Testing Laboratories inspectors.
The Board shall, examine carefully the cases referred to it by any Inspector under the Act, and provide an opportunity of hearing to the accused to explain his position before directing the inspector to prosecute the accused.

Before referring any case to the Drug Court, the Board shall ascertain the names of the directors, partners and employees of the company, corporation, firm or institutions who are prima facie responsible for the Commission of the offence under the Act, or the rules made there under and allow an Inspector to institute prosecution only against such persons.

Where a drug is found to be substandard or adulterated the Board, before referring the case to the Drug Court, on the request of the complainant or the accused, may cause a sample of the drug to be tested and analysed and provide an opportunity to the accused to explain his position in view of the contents of the report of the test.

Provided that where the retesting is ordered by the Board under this rule, the test results shall be final.

4. Qualifications etc of inspectors and Analyst. - (1) No person shall be appointed as an Inspector unless he possesses a degree in Pharmacy from a Pakistani University or any other institution recognised for this purpose by the Pharmacy Council of Pakistan and has at least one year’s experience in the manufacture, sale, testing or analyses of drugs or in the Drugs Control Administration or in a hospital or pharmacy.

(2) No person shall be appointed as an analyst unless he possesses a degree in pharmacy from a Pakistani University or any other institution recognised for this purpose by the Pharmacy Council of Pakistan and has at least five years experience in the manufacture testing or analysis of drugs or in the Drugs Control Administration.

Provided that if a person of the requisite qualification is not available, a person possessing a degree in Medicine or Master’s degree in Pharmaceutical Chemistry, Microbiology or Pharmacology with five years experience in testing of drugs and medicines in public health laboratories may be appointed.

Provided further that the provisions of this rule shall not apply to the Inspectors and Analyst who were appointed as such on regular basis before the coming into force of these rules.

Government may, by notification in the official Gazette, appoint a person possessing a degree in Pharmacy, Medicine or Masters degree in Pharmaceutical Chemistry or Microbiology or Pharmacology as an ex-officio Inspector from amongst its officers working in the Drugs Administration or in any other recognised Pharmacy or medical institution, who otherwise does not fulfill the qualifications laid down in sub-rule (1).

Provided that the ex-officio inspector shall be appointed for the purpose of—

(i) Conducting inspection of any premises wherein any drug is sold or is stocked or exhibited for sale or distribution;

(ii) conducting inspection of storage arrangements and relevant records and registers in such premises; and

(iii) taking samples of any drug which is being sold or is stocked or exhibited for sale or is being distributed.
Government may, by notification in the official Gazette, for the exercise of such powers as may be specified in the notification, appoint as ex-officio Analyst any person who holds a degree in Pharmacy or Medicine or Masters degree in Pharmaceutical Chemistry or Microbiology or Pharmacology and is engaged in testing and analysis in a Government Testing Laboratory or in a Chemical Examiner’s Laboratory or is working in a Pharmaceutical or Medical Educational or Research Institution.

5. Duties of Inspectors.—Subject to the instruction Of the licensing authority, it shall be the duty of an inspector.—

(a) to inspect not less than twice a year all establishments of drugs licensed for sale and one year all establishments licensed for manufacture of drugs within the area assigned to him, and to keep record of such inspections;

(b) to satisfy himself that the conditions of the licenses are being observed,

(c) to take and send for test or analysis, if necessary, samples of any drug where there is reason to suspect that the drug is being manufactured or sold, stocked or exhibited for sale in contravention of any of the provisions of the Act;

(d) to investigate any complaint in writing which may be made to him and furnish the report in respect thereof to the licensing authority;

(e) to institute prosecution in respect of contravention of the Act and these rules;

(f) to maintain record of all inspections made and actions taken by him in the performance of his duties, including the taking of samples and the seizure of stocks, and submit reports of such record as may be required by the licensing authority; and

(g) to make such enquiries and inspections as may be necessary to stop manufacture and sale of drugs in contravention of the Act and these rules.

6. Duties of analyst.—(1) An analyst shall cause to be analysed or tested such samples of drugs as may be sent to him under the Act, and shall furnish report of the results of test and analysis in Form 3 in accordance with the Act and these rules.

(2) An analyst shall cause to be tested and analysed such samples of drugs as may be sent to him in writing from a department of Government or any other public institutions and shall furnish the report or the report of test and analysis to the Department of the public institution concerned.

(3) An analyst shall forward monthly reports giving results of samples tested and analysed during the period under report with a view to their publication at the description of the Federal Government and furnish such other information as may be required by that Government.

7. Prohibition of disclosure of information.—Except for the purpose of official business or when required by a court of law. An inspector or an Analyst shall not disclose to any person any information acquired by him in the course of his official duties.

8. From of Order not to dispose of stock.— An order in writing by an Inspector under clause (i) of sub-section (1) of section 18 requiring a person not to dispose of any stock in his possession shall be in Form 4.

9. From of intimation of purpose of taking samples.—(1) Where an Inspector takes a sample of drug under clause (c) of sub-section (1) of Section 18 for the purpose of test or analysis, he shall
intimate such purpose in writing in Form 5 to the person from whom he takes it and where lie
seizes stock of a drug or other material under clause (f) of section 18 the receipt for such drug
and material shall be in Form 6.

(2) The inspector shall send a portion of the sample or the container to the analyst for test
or analysis under clause (i) of sub-section (3) of section 19 through a memorandum in
Form 7.

(3) In case the sample is delivered to the analyst by an indirect means such as post, a copy
of the memorandum, a specimen impression of the seal or mark used to seal the packet
together with the specimen impression of the person from whom the sample is drawn
shall be sent to the analyst separately by registered post or by hand.

10. Procedure on receipt of sample from Inspector.— On receipt of a package from an
Inspector containing a sample for test and analysis, the analyst shall compare the seal on the
packet with the specimen impression received separately and shall note the condition of the
seal on the package and after the test or analysis has been completed, he shall forthwith supply
and analysis with protocols under the Act.

11. Fee for test and analysis of drugs.—The fee for test and analysis of drugs in respect of
samples sent by persons other than an Inspector or a Government Institution shall be
determined by the analyst or the person incharge of the Government Laboratory in accordance
with the fees specified in Schedule “C”.

PART-III

SALE OF DRUGS.

12. Licensing Authority.— (1) The Secretary to Government of Health Department shall be the
licensing authority, for the purposes of these rules.

(2) The licensing authority may, by order in writing, authorise any person under his control
to sign the licence and to exercise such other powers, and in respect of such areas as
may be specified in the order.

13. Type of Licences to sell drugs.—The licenses under these rules shall be of the following
types, namely:—

(i) Licence to sell drugs by way of retail sale;
(ii) licence to sell drugs by way of wholesale;
(iii) licence to sell narcotics; and
(iv) licence to sell drugs in a pharmacy

14. Application for licence to Sale drugs and fees therefore.—(1) Application for the grant or
renewal of a licence referred to in rule 13 shall be made in Form 8 to the licensing authority.

(2) An application under sub-rule (i) shall be accompanied by a fee of two hundred rupees
in case of a fresh licence and one hundred rupees in case of a renewal.

(3) A fee of fifty rupees shall be paid for any change of proprietor or qualified persons or a
duplicate copy of the licence if the original is defaced, damaged or lost, and such copy of
the licence shall bear the words “duplicate copy”.

15. Form of licence to sell drugs—(1) A licence to sell, store, exhibit for sale or distribute drugs
by way of retail sale shall be issued in Form 9.
(2) A licence to sell, store, exhibit for sale or distribute drugs by way of whole sale shall be issued in Form 10.

(3) A licence to sell, store, exhibit for sale or distribute narcotics shall be in Form it.

(4) A licence to sell drugs in a pharmacy shall be in Form 12.

16. Sale at more than one place:— If drugs are sold, stored, exhibited for sale or distributed at more than one place, a separate licence shall be required in respect of each such place.

17. Duration of licence: — (1) A licence issued under these rules shall, unless sooner suspended or cancelled, remain in force for two years from the date of issue or until the disposal of the application for renewal of such licence whichever is later. An application of renewal of a licence shall be made within one month of the expiry thereof.

Provided that an application for renewal of a licence may be entertained by the licensing authority if such application is made within one month after the expiry of the licence and the licensing authority is satisfied that the application could not be made earlier for reasons beyond the control of the licence.

(2) An application for renewal of licence shall be disposed within three months of the receipt of such application.

18. Pre-conditions of the issue of licence.—(1) The licensing authority shall not issue —

(a) Licenses in Form 9 and From 12 unless:

(i) The premises have proper and adequate facilities for storage of drugs and for their protection from direct sunlight dust or dirt including refrigeration facilities where necessary for preserving the properties of the drugs to which the license applies;

(ii) The premises are clean and in hygienic and tidy condition; and

(iii) In the case of a pharmacy, the requirement laid down in schedule Fare complied with;

(b) Licences in Form 10 unless the applicant is an indentor, importer, manufacturer or distributor of a manufacturer drug and fulfils the conditions laid down in sub-clauses (i) and (ii) of clause (a) and (c) licence in Form 11 unless—

(i) the application posses a licence in form 9 or Form 10 or Form 11; and

(ii) the applicant has never been convicted of any offence under the act.

(2) The sale of drugs shall be supervised—

(a) Under licence ii Form 9 or Form 11 by a person—

(i) Who registered under section 24(1) (a) and (b) of the pharmacy Act, 1967 (XI of 1967) or

(ii) Who was approved as qualified person for grant of drug sales licence under the West Pakistan Drug Rules 1958 or

(iii) who was on the 19 iii day ofjune, 1972 qualified for registration under section 24 (1) (b) of pharmacy Act, 1957 (XI of 1976); or
(iv) who has before the commencement of these rules passed the examination, of compounder or dispenser and has completed two years period of apprenticeship under section 24(1)(c) of the Pharmacy Act, 1967

(b) Under license in Form 10 by a person

(i) who fulfils the conditions laid down in clause (a), or

(ii) Who has been a student or apprentice in pharmacy under clause (iii) of sub-section (2) of section 25 of the Pharmacy Act, 1967 (XI of 1967); Provided that this provision shall be applicable after 2 years of the commencement of these rules;

(c) under licence in From 12 by a person who is registered as pharmacist under section 24 (1) (a) of Pharmacy Act, 1967 (XI of 1967) or by a person who is registered under section 24 (1) (b) of pharmacy Act, 1967 (XI of 1967) and possesses at least 3 years experience in compounding.

19. Conditions of Licences—(1) Licences on Forms 9 and 12 shall be issued subject to the conditions stated therein and to the following general conditions, namely—

(a) the supply by way of retail sale of any drug shall be recorded suitably and such records bills or counterfoils shall be preserved for a period of at least three years from the late of such sale;

(b) drug specified in schedule ‘B’ and ‘D’ and preparations containing such drugs shall not be sold by retail sale, except on and in accordance with the prescription of a registered medical practitioner.

Provided that no such prescription shall be required for sale of these drug to a registered medical practitioner, hospital dispensary or any other institution approved by an order of the licensing authority for such sale:

(c) the sale of any drug specified in schedule ‘B’ and ‘D’ by way of retail sale shall be recorded at the time of supply in a register specialty maintained for the purpose and the serial No. of the entry in the register shall be entered in the prescription and the following particulars shall be entered in the register, namely.

(i) Serial No.

(ii) Date of sale.

(iii) Name of the prescriber.

(iv) Name of the patient/purchaser.

(v) Name of the drug.

(vi) Name of manufacturer.

(vii) Quantity.

(viii) Batch No.

(xi) Signature of the qualified person:
Provided that if the drug specified in schedule (D) is sold on a prescription on which the drug has been sold on a previous occasion, it shall be sufficient if the entry in the register includes Serial No. the date of sale, the quantity sold, and sufficient references to an entry in the register recording the dispensing of the drug on a previous occasion.

(2) For the purpose of this rule, a prescription shall
(a) be in writing and be signed by the person giving it with his usual signature and be dated by him.
(b) specify the name and address of the person for whose treatment it is given and
(c) indicate the total quantities of drugs to be supplied and the doses to be taken

(3) All invoices and bills of purchase of drugs shall be preserved for a period of at least three years.

(4) Records shall be maintained of all purchases and sales of drugs by way of wholesale and such records shall be preserved for three years and shall include the following particulars, namely—
(a) The date of purchase and sale;
(b) the name and address of the concern from which purchase and the concern to which sold;
(c) the names of the drugs, their batch No. their dates of expiry, where applicable and the quantities and
(d) the name of the manufacturer.

(5) Except as otherwise provided in these rules, all registers and records maintained under these rules shall be preserved for a period of not less than three years from the date of last entry.

(6) The licensee shall produce for inspection by an Inspector on demand all registers and records maintained under these rules, and shall supply to the inspector such information as he may require.

(7) Substances specified in Schedule ‘E’ and falling under the list of poison and those specified in schedule ‘B’ shall be stored in the retail shop—
(a) in part of the premises to which customers do not have access or
(b) in a almirah or cupboard or drawer locked an reserved solely for the storage of such drugs.

(8) Substance falling under the list of poisons in Schedule ‘E’ shall be stored in containers impervious to the poison and sufficiently stout to prevent leakage arising from the ordinary risks of handling and transport.

(9) A substance falling in the list of poison under Schedule ‘E’ when compounded and dispensed, shall be labelled with the word “poison”

20. Cancellation and suspension of licences. (1)—The licensing authority may, on the report of an inspector or on its own motion, after giving the licensee an opportunity to show cause, by an order in writing stating the reasons there for, cancel a licence issued under these rules or suspend it for such period as it thinks fit, either wholly or in respect of some of the drugs to
which it relates, if in its opinion, the licensee has failed to comply with any of the condition of the license or with any of the provisions of the Act or these rules when the offence is of serious nature.

(2) A licensee whose licence has been cancelled or suspended may, appeal to the appellate Board within sixty days of the date of such order.