

## NOTIFICATION

Islamabad, the 27th October, 1996

S.R.O. 1214(I)/96.- In exercise of the powers conferred by sub-section (1) of section 44 of the Drugs Act, 1975 (XXXI of 1976), the Chief Executive, Northern Areas is pleased to make the following Drugs Rules, namely:-  
The Northern Areas Drugs Rules, 1996.

### PART I.-PRELIMINARY

**1. Short title and commencement.-** (1) These rules may be called the Northern Areas Drugs Rules, 1996.  
(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) "Board" means the Northern Areas Quality Control Board;
- (c) "Form" means form prescribed in Schedule "A".
- (d) "Government" means the Kashmir Affairs and Northern Affairs Division and Northern Areas Administration;
- (e) "Narcotic and other controlled drugs" means the drug specified in Schedule "B".
- (f) "Pharmacy" means a shop, store or place where drugs are compounded or prepared on prescription; it shall include a place which bears the words. Pharmacy, Pharmacist or dispensing chemist and shall conform to requirement laid down in Schedule "F".
- (g) "Registered Medical Practitioner" means a medical practitioner registered under the Pakistan Medical and Dental Council Ordinance, 1962 (XXXII of 1962);
- (h) "Schedule" means a schedule to these rules;
- (i) "section" means section of the Act; and
- (j) "Whole Sales" sale by way of whole sale dealing, means, sale to a person who buys for the purpose of selling again.

### PART II.-NORTHERN AREAS QUALITY CONTROL BOARD GOVERNMENT ANALYST AND DRUG INSPECTOR.

#### 3. Northern Areas Quality Control Board.-

(1) The Board shall consist of the following members, namely:-

- |  |           |
|--|-----------|
| (a) Director Health Services, Northern Areas, Gilgit                       | Chairman  |
| (b) Medical Superintendent, District Health Officer, Hospital Gilgit       | Member    |
| (c) Deputy Commissioner, Gilgit  | Member    |
| (d) Drug Inspector, Directorate of Health Services Northern Areas, Gilgit. | Secretary |

(2) The Board may co-opt any other qualified expert having formal training and experience in the Pharmaceutical field.

(3) The quorum to constitute a meeting of the Board shall be three including its Chairman.

(4) No act or proceeding of the Board shall be invalid merely on the ground of the existence of any vacancy in or any defect in the constitution of the Board.

**4. Functions of the Board.-**(1) The Inspector and the Government Analyst shall submit monthly returns in Form-1 and Form-2 respectively, to the Board and a summary on the over all situation of quality control in the area under their respective jurisdiction and the Board shall maintain such information so as to monitor the quality of all the drugs sold and to keep watch on the performance of all manufacturers and the drugs sale licence holder.

(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 whole including consideration of any specific point arising during the period on the working of various Firms. Drug Testing Laboratories and Inspectors.

(3). The Board shall examine the cases referred to it by any Inspector under the Act before directing him to prosecute such accused or recommending to the Licensing Authority for cancellation or suspension of the licence, provided that no such action shall be taken without a show cause notice to the accused.

(4) Before referring any case to the Drug Court, the Board shall ascertain the name of the Directors, Partners and employees of the Company, Corporation, Firms or institutions who are prima facie responsible for the commission of the offence under the Act or the rules and allow an Inspector to institute prosecution only against such persons.

(5) The Board may in view of minor contravention of offences in its discretion, advise the accused to make improvement, or if considered necessary, issue a warning to the accused.

**5. Qualifications of Inspectors and Analyst.-** (1) No person shall be appointed as a Inspector unless he posses 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 experience in the manufacture, retail sale testing or analysis of drug or in the Drug Control Administration or in a Hospital Pharmacy:

Provided that for dealing with specific cases, the Government may appoint as ex-officio inspector any Gazetted Officer of Medical or Public Health Department, who is a Registered Medical Practitioner, or any officer working in the Health Administration, who has a degree in medicine or pharmacy or any other person having similar qualification and is working as a teacher in Pharmacy or Medical Education:

Provided further that the ex-officio Inspector shall be appointed for the purpose of conducting inspection of:-

- (i) any premises wherein any drug is sold or is stocked or exhibited for sale or distribution;
- (ii) the storage arrangements and all relevant records registers; and
- (iii) taking samples of any drug which is being sold or is stocked or exhibited for sale or is being distributed.

(2) No person shall be appointed as an Analyst unless he possesses a Degree in Pharmacy from a Pakistani University or any other Institution recognized for this purpose by the Pharmacy Council of Pakistan and has at least five years experience preferably in the manufacture, testing or analysis of drugs or in the Drugs Control Administration;

Provided that the provisions of these rules shall not apply to the Analysts who were appointed as such on regular basis before the coming into force of these rules.

**6. Duties of Drug Inspector.-** Subject to the instructions of the Licensing Authority, it shall be the duty of Drug Inspector:-

(a) to inspect not less than twice a year all establishments of drugs licenced for sale and all establishments licenced 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 licences are being observed;

(c) to take and send for test or analysis if necessary, samples of any drug which he has reason to suspect is being manufactured, 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; and

(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 seizure of stocks, and submit report of such record as may be required by the Quality

Control Board.

**7. Prohibition of Disclosure of Information.-** Except for the purpose of official business or when required by the Court of Law, an Inspector or any Analyst shall not disclose to any unauthorised person any information acquired, by him in the course of his official duties.

**8. Form of order not to dispose off stock.-** An order in writing by an Inspector under clause (I) of sub-section (1) of section 18 of the Act, requiring a person not to dispose of any stock in his possession shall be in Form-3.

**9. Form of intimation for the purpose of taking samples.-** (1) Where an Inspector takes a sample of drugs under clause (c) of sub-section (1) of section-18 of the Act, for the purpose of test or analysis, he shall intimate such purpose in writing in Form-4, to the person from whom he takes it and where he seizes stock of drug or other material under clause (f) of section 18 of the Act, the receipt for such drugs and material shall be in Form-5.

(2) The Inspector shall send a portion of the sample or the container to the Analyst for test and analysis under clause (I) of sub-section (3) of section 19 of the Act, through a memorandum in Form-6.

(3) The Inspector shall send a specimen impression of his seal to the Analyst and shall inform him of any change.

**10. Powers to transfer cases.-** Where an offence is found to have been committed in an area outside the jurisdiction of an Inspector, he shall transfer the case with all details and material to the concerned Inspector for conducting investigation and prosecution as may be considered necessary.

**11. Duties of Government 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, the result of test and analysis on Form-7, in accordance with 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 Government Department or any other public institution and shall furnish the report of the result of test and analysis to the Government Department or the public institution concerned.

(3) An Analyst shall forward monthly report giving results of samples tested and analysed during the period under report for publication at the discretion of the Federal Government and furnish such other information as may be required by that Government.

**12. Procedure on receipt of samples from Inspector.-** On receipt of a package from an Inspector containing a sample for test and analysis, the Analyst shall compare the seals 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 to the Inspector a report of the result of the test and analysis.

**13. Fee for test and analysis of drugs.-** The fee for test and analysis of drugs in respect of samples sent by a person other than an Inspector or a Government Institution shall be determined by the Government Analyst or the person Incharge of the Government Laboratory in accordance with the fees specified in Schedule "C".

### **PART III.-SALES OF DRUGS**

**14. Licensing Authority.-** (1) The Chief Inspector of Drugs or Secretary Quality Control Board will be the drugs licensing authority for all type of drug sale licence within the area of his jurisdiction.

**15. Type of Licences to sell Drugs.-** The licences under these rules shall be of the following types, namely:-

- (i) licence for drugs by way of retail sale;
- (ii) licence for drugs by way of whole sale;
- (iii) licence for narcotics and other controlled drug; and
- (iv) licence for drug in a Pharmacy.

**16. Application for licence to sell Drug and fees thereof.-** (1) Application for the grant or renewal of a licence referred to in clause (I) to (iv) of rule 15 shall be made in Form-8, to the licensing authority. The fee shall be charged as under:-

(a) one thousand rupees for the grant of a licence to sell either the drugs specified in the clause (I) to (iv) of rules 15; and

(b) five hundred rupees in case of renewal of such licence subject to the condition that the provisions of these rules have been complied with.

(2) A fee of five hundred rupees shall be paid for a change of a qualified person and a duplicate copy of the licence referred to in clause (I) to (iv) of rule 15, if the original is defaced, damaged or lost and such copy of the licence shall bear the words "duplicate copy."

(3) The fees so collected will be utilised as under:-

(i) fifty per cent of the fee shall be deposited into Government Treasury under the relevant Head of Accounts; and

(ii) remaining fifty per cent of the fee shall be utilised on day to day expenses for collection of samples, packing and parceling of the samples to the Government Testing Laboratories, besides other petty expenditure in the Chief Drug Inspectors office, proper Accounts of the same will be maintained accordingly.

**17. Forms of Licences 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, and other controlled drugs shall be in Form-II.

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

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

**19. Duration of licences.-** (1) A licence issued under these rules shall unless suspended or cancelled earlier, remain in force for two years-from the date of issue, and if an application for renewal of such licence is not made within one month of its expiry of the licence shall stand cancelled.

Provided that if an application for renewal of a licence is made before the expiry of the period of its validity or where it is not done so far, reasons beyond the control of the licence and the application is made within one month of the expiry of the licence shall continue to be in force, until orders are passed on the application.

(2) An application for renewal shall be disposed of within three months of the receipt of such application after receiving inspection report from the Inspector concerned.

**20. Pre-conditions for the issue of licence.-** (1) The licensing Authority shall not issue:-

(a) Licences in Form-9 and Form-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;

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

(iii) in the case of Pharmacy, the requirements laid down in Schedule "F" are complied with.

(b) Licences in Form-10 unless the appoint is an indenter, importer, manufacturer or distributor of drugs and fulfills

the conditions laid down in sub-clause (a); and

(c) licence in Form-II, unless:-

(i) the applicant possesses a licence in Form-9, Form-10 or Form-12; and

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

(2) The sale of drugs in Forms 9, 10, 11 and 12 shall be supervised by a person who is registered under clause (a) and (b) of sub-section (1) of section 24 of the Pharmacy Act, 1967 (XI of 1967).

(3). In the case of renewal of already licenced premises, the licence shall not be renewed unless they employ on whole-time basis a qualified person as mentioned in sub-rule (2).

**21. Conditions of licences.-** (1) Licences in Forms 9, 10, 11 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 date of such sale, and

(b) drugs 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 with the Pakistan Medical and Dental Council. A prescription shall be dispensed only once, unless or otherwise specifically directed by the prescriber to repeat it:

Provided that no such prescription shall be required for sale of these drugs 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 specially maintained for the purpose and the serial number 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 number.

(ii) date of sale.

(iii) name of the prescriber.

(iv) name of the patient or purchaser.

(v) name of the drug.

(vi) name of the manufacturer.

(vii) quantity.

(viii) batch No.

(ix) 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 number, the date of sale, the quantity sold and a sufficient reference 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 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 reserved for a period of at least three years.
- (4) In case of sale of drugs by way of whole sale by manufacturer of their authorised dealers, they must invariably ensure that the purchaser holds a valid Drug Sale Licence, and shall issue an invoice and warranty at the time of sale of drug;
- (5) The whole seller while selling drugs to a retailer must also invariably ensure that the retailer holds a valid Drug Sale Licence as required under the Act and these rules and shall issue an invoice and warranty at the time of sale of drugs.
- (6) The invoice and warranty must bear the full name and address of the purchaser and shall be signed by the warrantor clearly indicating his name and must be dated.
- (7) Records shall be maintained of all purchases and sale of drugs by way of whole sale 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 purchased and the concerns to whom sold;
  - (c) the name of the drugs, their batch number, their dates of expiry where applicable and the quantities; and
  - (d) the name of the manufacturer.
- (8) 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 five years from the date of last entry.
- (9) The licence shall produce for inspection on demand by an Inspector all registers and records maintained under these rules, and shall supply to the Inspector such information as he may require.
- (10) Substances specified in Schedule 'E' and falling under the list of poisons and those specified in Schedule 'B' shall be stored in the retail shop:-
- (a) in a part of premises to which customers do not have access; or
  - (b) in an almarah, cupboard or drawer locked and reserved solely for the storage of such drugs.
- (11) Substance falling under the list of poisons in Schedule 'E' shall be stored in containers, impervious to the poison, and sufficient stout to prevent leakage arising from the ordinary risks of handling and transport.
- (12) A substance falling in the list of poisons under Schedule 'E' when compounded and dispensed, shall be labelled with the word "Poison."

22. Cancellation and suspension of licences.- (1) The Licensing Authority may, on the report an Inspector or the Board, after giving the licensee an opportunity to show cause by an order in writing stating the reasons therefore, cancel a licence issued under these rules or suspend it for such period as it thinks fit, if in its opinion the licensee has failed to comply with any of the conditions of the licence or with any of the provisions of the Act or these rules.

(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.

[No. 10/5/96-NA.I.]