(Department of Mines and Fuel)

ORDER

New Delhi, the 4th May 1960

S.O. 1193.—In exercise of the powers conferred by section 5 of the Essential Commodities Act, 1955 (10 of 1955), the Central Government hereby direct that the powers conferred on it by section 3 of the said Act to make orders under clauses (c), (d), (e), (f), (h), (i) and (j) of sub-section (2) of that section shall, in relation to all petroleum products (other than Kerosene), be exercisable also by the Chief Commissioner of Manipur and with the previous consent of the Chief Commissioner, by the Deputy Commissioner, Manipur, within the Union Territory.

2. This order shall remain in force for a period of six months commencing on and from the date of its publication in the Gazette of India.

[No. 115(11)/60-PPD.]

S. K. MUKHERJEE, Dy. Secy.

MINISTRY OF HEALTH

New Delhi, the 26th April 1960

S.O. 1194.—The Medical Council of India having elected Dr. U. C. Bardoloi, M.D., D.R.C.O.G.(Lond.), DOG, LM, formerly Director of Health Services, Shillong to be a member of the Indian Nursing Council under clause (d) of sub-section (1) of Section 3 of the Indian Nursing Council Act, 1947, *vice* Dr. K. N. Misra, the Central Government in pursuance of sub-section (1) of section 3 of the said Act, hereby makes the following amendment in the notification of the Government of India, Ministry of Health, No. F. 27-57/57-MII(B), dated the 1st December, 1958, namely:—

In the said notification, under the heading "elected under clause (d) of sub-section (1) of section 3" for the existing entry the following entry shall be substituted, namely:—

"Dr. U. C. Bardoloi, M.D., D.R.C.O.G. (Lond.), DOG, LM, former Director of Health Services, Shillong.

[No. F. 27-15/60-MII.]

R. MURTHI, Under Secy.

New Delhi, the 28th April 1960

S.O. 1195.—The Government of Orissa having nominated Shri R. B. Pany, Drugs Inspector, Eastern Range, Orissa to be the representative of that Government on the Drugs Consultative Committee in place of Shri V. L. Narasimha Rao, the Central Government, in pursuance of section 7 of the Drugs Act, 1940 (23 of 1940), hereby makes the following further amendment in the notification of the Government of India in the Ministry of Health No. F. 1-3/47-DII, dated the 13th September, 1948, constituting the Drugs Consultative Committee, namely:—

In the said notification, under the heading 'Nominated by State Government', for entry 8 the following entry shall be substituted, namely:—

"(8) Shri R. B. Pany, Drugs Inspector, Eastern Range, Orissa."

[No. F. 4-5/60-D.]

New Delhi, the 6th May 1960

S.O. 1196.—In exercise of the powers conferred by sections 6, 12 and 33 of the Drugs Act, 1940 (23 of 1940), the Central Government hereby makes the following further amendments in the Drugs Rules, 1945, the same having been previously published as required by the said sections, namely:—

In the said rules—

1. in rule 2, after clause (c) the following clause shall be inserted namely:—

"(ee) "registered medical practitioner" means a person—

(i) holding a qualification granted by an authority specified or notified under section 3 of the Indian Medical Degrees Act, 1916 (7 of 1916), or specified in the Schedules to the Indian Medical Council Act, 1956 (102 of 1956); or

(ii) registered or eligible for registration in a medical register of a State meant for the registration of persons practising the modern scientific system of medicine; or

(iii) registered in a medical register of a State, who although not falling within sub-clause (i) or sub-clause (ii) is declared by a general or special order made by the State Government in this behalf as a person practising the modern scientific system of medicine for the purposes of this Act; or

(iv) registered or eligible for registration in the register of dentists for a State under the Dentists Act, 1948 (16 of 1948); or

(v) who is engaged in the practice of verterinary medicine and who possesses qualifications approved by the State Government";

in rule 61.

(a) to sub-rule (1) the folowing proviso shall be added, namely:—

"Provided that a licence in form 20A shall be valid for only such drugs as are specified in the licence";

(b) to sub-rule (2) the following proviso shall be added, namely:—

"Provided that a licence in form 21-A shall be valid for only such drugs as are specified in the licence";

3. for rule 69, the following rule shall be substituted, namely:—

"69. *Application for licence to manufacture drugs other than those specified in Schedules C and C (1) to the Drug Rules.*—(1) Applications for the grant or renewal of licences to manufacture for sale of drugs other than those specified in Schedules C and C(1) shall be made to the licensing authority appointed by the State Government for the purpose of this Part (hereinafter in this Part referred to as the licensing authority) and shall be made—

(a) in the case of repacking of drugs for sale or distribution, in Form 24-B; and

(b) in any other case, in Form 24.

(2) Every application in Form 24-B shall be accompanied by a fee of rupees forty, and every application in Form 24 shall be accompanied by a fee of rupees two hundred.

(3) If a person fails to apply for the renewal of his licence before the date of its expiry, the fee payable for the renewal of such licence shall be, in the case of Form 24-B, rupees forty plus an additional fee of rupees twenty, and, in the case of Form 24, rupees two hundred plus an additional fee of rupees hundred.

(4) A fee of rupees ten and a fee of rupees fifty shall be paid respectively for a duplicate copy of the licence issued under clause (a) and clause (b) of sub-rule (1), if the original is defaced, damaged or lost.

(5) Applications by licensees to manufacture additional categories of drugs shall, in the case of a licence to manufacture for sale and distribution other than repacking, be accompanied by a fee of rupees ten for each category of drugs specified in Schedule M.

Explanation.—For the purpose of these rules, the term 'repacking' means the process of breaking up any drug from a bulk container into small packages and the labelling of each such package with a view to its sale and distribution, but does not include the compounding or dispensing or the packing of any drug in the ordinary course of the retail business".

4. for rule 70, the following shall be substituted, namely:—

"70. *Form of licence to manufacture drugs other than those specified in Schedules C and C(1).*—Licences for repacking of drugs against applications in Form 24-B shall be granted in Form 25-B, and licences for manufacture for sale and distribution against applications in Form 24 shall be granted in Form 25.";

5. after rule 71 the following rule shall be inserted, namely:—

"71-A. *Conditions for the grant or renewal of a licence in Form 25-B.*— Before a licence in Form 25-B is granted or renewed the following conditions shall be complied with by the applicant:—

(1) The repacking operation shall be carried out under hygienic conditions and under the supervision of a competent person;

(2) adequate space and equipment shall be provided, and

(3) the applicant shall have (i) either adequate arrangements in his own premises for carrying out the tests for strength, quality and purity of the drugs, or (ii) make arrangements with some institution approved by the licensing authority for such tests to be regularly carried out on his behalf by that institution.

Explanation.—A person who satisfies the following minimum qualifications shall be deemed to be a "competent person" for the purposes of rules 71-A or 74-A of these rules, namely:—

(a) a person who holds the Diploma in Pharmacy approved by the Pharmacy Council of India under the Pharmacy Act, 1948 (VIII of 1948) or a person who is registered under the said Act, or

(b) a person who has passed the Intermediate examination with Chemistry as one of the principal subjects or an examination equivalent to it or an examination recognised by the licensing authority as equivalent to it, or

(c) a person who has passed the Marticulation examination or an examination recognised by the licensing authority as equivalent to it and has had not less than four years practical experience in the manufacture, dispensing or repacking of drugs."

6. in rule 72, after the word and figures 'Form 25' the words, figures and letter 'or in Form 25-B' shall be inserted;

7. after rule 73-A, the following rule shall be inserted, namely:—

"73-B. *Certificate of renewal of licence in form 25-B.*—The Certificate of renewal of a licence in Form 25-B shall be issued in Form 26-B.";

8. after rule 74, the following rule shall be inserted, namely:—

"74-A. *Conditions for licence in Form 25-B.*—A licence in Form 25-B shall be subject to the conditions stated therein and to the following conditions:—

(a) the repacking of drugs shall be at all times be conducted under the personal supervision of at least one person who is approved as a competent person by the licensing authority;

(b) the licensee shall either provide and maintain adequate arrangements in his own premises for carrying out tests of the strength, quality purity of the drugs repacked or make arrangements with some institution approved by the licensing authority for such tests to be regularly carried out on his behalf by the institution;

(c) the licensee shall make adequate arrangements for the storage of drugs;

(d) the licensee shall comply with the provisions of the Act and of these rules and with such further requirements, if any, as may be specified by any rule subsequently made under Chapter IV of the Act of which the licensing authority has given the licensee not less than four months' notice;

(e) the licensee shall allow any Inspector authorised by the licensing authority in that behalf, to enter with or without notice, any premises where the repacking of drugs in respect of which the licence is issued is carried on, to inspect the premises and to take samples of repacked drugs;

(f) the licensee shall maintain detailed records of repacking of drugs and records of tests applied thereto, in such manner as the licensing authority may direct and the licensee shall allow an Inspector to inspect all such registers and records maintained under these rules and shall supply to the Inspector such information as he may require for the purpose of ascertaining whether the provisions of the Act and these rules have been observed.

9. in rule 109, for sub-rule (1), the following shall be substituted, namely:—

"(1) The following particulars and such further particulars, if any, as are specified in Schedule F shall be printed or written in indelible ink on the label of every phial, ampoule or other container of a substance specified in Schedule C and on every other covering in which such phial, ampoule or container is packed,—

(a) the proper name of the substance in letters not less conspicuous than those in which the proprietory name, if any, is printed or written and the following immediately after or under such proprietory name;

(b) the number of every licence under which the substance is manufactured or imported, preceded in the case of import licences by the word "Import Licence":

Provided that no reference shall be made to any other import licence number granted by any authority outside India on any label or container or in any covering in which the container is packed or in any other matter of advertisement enclosed therewith;

(c) a distinctive batch number, that is to say, the number by reference to which the prescribed tests, and details of manufacture of the particular batch from which the substance in the container is taken are permanently recorded and available for inspection; the figure representing the Batch Number shall be preceded by the words "Batch Number" or "Batch No." or "Batch" or "Lot Number" or "Lot No." or "Lot";

(d) where a test for potency in units is required by these rules, a statement of the potency in units defined in terms of relation to the standard preparation specified in Schedule F:

Provided that this clause shall not apply in the case of vaccine lymph or surgical ligature or suture;

(e) where a test for potency or maximum toxicity is required the date upto which the substance if kept under suitable conditions may be expected to retain a potency not less than that stated on the label of the container, or not to acquire a toxicity greater than that permitted by the test, as the case may be:

Provided that nothing in these rules shall be deemed to require the labelling of any transparent cover on any wrapper, case or other covering used solely for the purpose of packing, transport or delivery.";

(ii) clause (d) of sub-rule (3) shall be omitted.

10. in Schedule A.

(a) in form 19-A for paragraph 3, the following shall be substituted, namely:

"3. Names or classes of drugs proposed to be sold.";

(b) in Form 20-A, in paragraph 1, for the words 'drugs other than' the words 'the following drugs being drugs other than' shall be substituted;

(c) in Form 20-B, after condition 3, the following condition shall be inserted, namely:—

"4. Where the licensee is an agent for distribution of the drugs of a manufacturer, the sale by way of wholesale dealing of such drugs shall be covered by a warranty either in Form 22 or Form 23 to the effect that the drugs sold do not contravene the provisions of section 18 of the Drugs Act, 1940";

(d) in Form 21-A, in paragraph 1, for the words "drugs specified" the words 'the following drugs being drugs specified' shall be substituted;

(e) in Form 21-B, after condition 4, the following condition shall be inserted, namely:—

"5. Where the licensee is an agent for distribution of the drugs of a manufacturer, the sale by way of wholesale dealing of such drugs shall be covered by a warranty either in Form 22 or Form 23 to the effect that the drugs sold do not contravene the provisions of section 18 of the Drugs Act, 1940.";

(f) after Form 24-A, the following form shall be inserted, namely:—

"FORM 24-B

(*See* rule 69)

Application for grant or renewal of a licence to repack for sale or distribution drugs, being drugs other than those specified in Schedules C and C(1).

1. I/We ..... of ..... hereby apply for grant/renewal of a licence to repack the following drugs at the premises situated at .....

2. Names of the drugs to be repacked .....

3. Name, qualification and experience of competent staff .....

4. A fee of Rs. forty has been credited to Government under the head of account .....

Date Signature of applicant.

NOTE.—The application shall be accompanied by a plan of the premises.";

(g) in Form 25, after condition 3, the following condition shall be inserted namely:—

"4. The sale by way of wholesale dealing of drugs manufactured under this licence shall be covered by a warranty either in Form 22 or Form 23 to the effect that the drugs sold do not in any way contravene the provisions of section 18 of the Drugs Act, 1940.";

(h) in Form 25-A, after condition 3, the following condition shall be inserted; namely:—

"4. The sale by way of wholesale dealing of drugs manufactured under this licence shall be covered by a warranty either in Form 22 or Form 23 to the effect that the drugs sold do not in any way contravene the provisions of section 18 of the Drugs Act, 1940.";

(i) after Form 25-A, the following form shall be inserted, namely:—

"FORM 25-B

(*See* rule 70)

Licence to repack for sale or distribution of drugs being drugs other than those specified in Schedules C and C(1).

Number of licence and date of issue .....

1. ..... of ..... is hereby granted a licence to repack the following drugs for sale or distribution on the premises situated at ..... under the supervision of the following competent staff.

(a) Names of drugs to be repacked.

(b) Names of competent staff.

2. The licence shall be in force for a period of 2 years from the date of issue.

3. The licence authorises the sale by way of wholesale dealing by the licensee and storage for sale by the licensee of the drugs repacked under the licence subject to conditions applicable to licences for sale.

4. The licence is subject to the conditions stated below and to such other conditions as may be specified in the Rules for the time being in force under the Drugs Act, 1940

Date Signature .....

Designation .....

Conditions of license

1. This licence and any certificate of renewal in force shall be kept on the licensed premises and shall be produced at the request of any Inspector appointed under the Drugs Act, 1940.

2. Any change in the competent staff named in the licence shall be forthwith reported to the licensing authority.

3. If the licensee wants to repack for sale or distribution additional items he should apply to the licensing authority for the necessary endorsement to this licence. This licence shall be deemed to extend to only those items so endorsed.

4. The drugs repacked under this licence shall bear on their label, apart from other particulars required by these rules, the name and address of the licensee and the number of the licence under which the drug is repacked preceded by the words "Rpg. Lic. No."

5. The sale by way of wholesale dealing of drugs repacked under this licence shall be covered by a warranty either in Form 22 or 23 to the effect that drugs sold do not in any way contravene the provisions of Section 18 of the Drugs Act, 1940.";

(j) after Form 26-A, the following form shall be inserted, namely:—

"FORM 26-B

(See rule 73-B)

Certificate of renewal of licence to repack for sale or distribution of drugs being drugs other than those specified in Schedules C and C(1).

1. Certified that licence No. ..... granted on the ..... to ..... for the repacking of the following drugs at the premises situated at ..... has been renewed for a period of two years from the .....

Names of drugs to be repacked .....

2. Names of competent staff .....

Date

Signature

Designation.";

(k) in Form 28, after condition 3, the following condition shall be inserted, namely:—

"4. The sale by way of wholesale dealing of drugs manufactured under this licence shall be covered by a warranty either in Form 22 or Form 23 to the effect that the drugs sold do not in any way contravene the provisions of section 18 of the Drugs Act, 1940.";

(l) in Form 28-A, after condition 3, the following condition shall be inserted, namely:—

"4. The sale by way of wholesale dealing of drugs manufactured under this licence shall be covered by a warranty either in Form 22 or Form 23 to the effect that the drugs sold do not in any way contravene the provisions of section 18 of the Drugs Act, 1940.";

11. in Schedule C, for item 12, the following shall be substituted, namely:—

"Any other preparation which is meant for parenteral administration either in the form in which it is marketed or after being made up with a suitable solvent or medium.";

12. in Schedule C(1), for items 1 to 9 the following shall be substituted, namely:—

"1. Drugs belonging to the Digitalis group and preparations containing drugs belonging to the Digitalis group not in a form to be administered parenterally.

2. Ergot and preparations containing Ergot not in a form to be administered parenterally.

3. Adrenaline and preparations containing Adrenaline not in a form to be administered parenterally.

4. Fish Liver Oil and preparations containing Fish Liver Oil.

5. Vitamins and preparations containing any vitamins not in a form to be administered parenterally.

6. Liver extract and preparations containing liver extract not in a form to be administered parenterally.
7. Hormones and preparations containing Hormones not in a form to be administered parenterally.
8. Vaccine not in a form to be administered parenterally.
9. Following drugs and preparations containing them not in a form to be administered parenterally:—
   (1) Penicillin.
   (2) Streptomycin.
   (3) Chlortetracysline.
   (4) Oxytetracycline.
   (5) Chloramphenicol.
   (6) Neomycin.
   (7) Carbomycin.
   (8) Erythromycin.
   (9) Bacitracin.
   (10) Tetracycline.
   (11) Gramicidin.
   (12) Tyrothricin.
   (13) Viomycin.";

13. in Schedule F after Part XII, the following part shall be inserted, namely:—

"PART XII-A"

Provisions applicable to Antibiotics and their preparations.

Injection of procaine Benzyl Penicillin in Oil with Aluminium Stearate suspension.

Injection of Procaine Benzyl Penicillin in Oil with Aluminium Stearate Suspension is a sterile suspension of procaine benzyl penicillin in a suitable oil containing 2% w/v of aluminium monosterate. It contains not less than 90% of the number of International Units of Penicillin stated on the label.

Proper Name.—The proper name shall be "Injection of Procaine Benzyl Penicillin in Oil with Aluminium Stearate Suspension" or "Sterile Procaine Penicillin G with Aluminium Stearate Suspension".

Consistence.—Passes readily through a hypodermic needle of internal diameter 0.895-0.905mm at 25°C.

Particle size.—The diameter of not less than 65% of the particles does not exceed 5 microns.

Stability.—When shaken by hand it forms a suspension which is stable for 48 hours at 37°C; if any separation takes place during this time, the thickness of the oily layer should not be greater than 3 mm.

Water.—Not more than 1·4%.

Sterility.—After the addition of a quantity of solution of penicillinase or other suitable inactivating agent adequate to ensure complete inactivation of the penicillin present, complies with the test for sterility.

Blood-level Duration.—When determined as described in the Appendix, a quantity equivalent to 300,000 International Units of penicillin produces blood-serum levels at 72 hours of not less than 0·03 International Units per ml in not less than half the number of subjects used.

Other Requirements.—Complies with the requirements stated under "Injections" in the Indian Pharmacopoeia.

Assay.—The potency is determined by the method included in the Appendix.

Storage.—Injection of Procaine Benzyl Penicillin in Oil with Aluminium Stearate Suspension should be stored in a cool place, but not in a refrigerator.

Labelling.—The label on the container must state (1) the name of the injection; (2) the number of International Units in 1 ml; (3) "For intramuscular use only".

When Injection of Procaine Benzyl Penicillin in Oil with Aluminium Stearate Suspension is prescribed, no strength being stated, the injection containing 300 000 International Units per ml shall be dispensed.

APPENDIX

Blood-level duration test

1. *The Test.*—Ten or more persons in good health and weighing between 60 and 90 kg who have not taken penicillin or similar antibiotics in any form during the previous seven days are selected as test subjects. Each subject is injected with a quantity of the Injection of Procaine Benzyl Penicillin in Oil with Aluminium Stearate Suspension under test equivalent to 300,000 International Units of penicillin. A 5 ml sample of venous blood is withdrawn 72 hours after the injection and if desirable, at other times during the test period; the subject should receive no other antibiotic during this period. The blood is allowed to clot and the serum is separated by contrifuging and transferred immediately to a sterile tube. If it is not to be tested on the same day, the serum is frozen at 20°C or below and stored frozen. The penicillin content of the samples of serum is determined as described below:—

2. *The Blood-serum Assay (Sarcina Lutea Method).*—The antibiotic potency of a sample of serum presumed to contain penicillin is determined by comparing the volumes of it required to inhibit the growth of a standard strain of Sarcina Lutea with the quantities of a standard preparation of penicillin required to produce the same degrees of inhibition.

Working Standard Solution

To about 0·015 g of the International Standard preparation of penicillin, accurately weighed in an atmosphere of 50% relative humidity or less, sterile 1% phosphatebuffer, pH 6·0 is added to make a stock solution containing 0·6 mg per ml. (1,000 International Units per ml). This solution is kept at a temperature of about 10°C and used for two days only. On the day of the assay, this stock solution is diluted to 1·0 International Units per ml using the above-mentioned buffer. Working dilutions of the latter solution are prepared using as the diluent bovine albumin TS which, before use, has been filtered through a bacteria-proof filter and tested on plates for inhibition of Sarcina Lutea under the conditions outlined below. Boving albumin TS which shows inhibition under these conditions should not be used.

Preparations of serum samples

Serum samples expected to contain not more than 0·4 International Unit per ml need not be diluted. Samples expected to have a potency greater than 0·4 International Unit per ml should be diluted to about 0·1 International Unit per ml with bovine albumin TS known to have no antibiotic activity.

Suggested Method

The general procedure described under "Biological Assay of penicillin" is applied with the specific changes set forth below.

Media:

Nutrient agar for the base layer and for carrying the test organism is prepared as follows:—

Peptone	6·0 g
Pancreatic Casein digest	4·0 g
Yeast extract	3·0 g
Beef Extract	1·5 g
Glucose	1·0 g
Agar	15·0 g
Water, sufficient to product	1,000 ml.

The reaction is adjusted so that the pH is 6.5 to 6.6 after autoclaving at 121°C for 20 minutes.

Agar for the inoculated layer is prepared as above, but omitting the pancreatic digest of casein and adjusting the reaction so that the pH is 6·5 to 6·6 after autoclaving.

Nutrient broth for preparing an inoculum of the test organism is prepared as follows:—

Peptone	5·0 g
Yeast Extract	1·5 g
Beef Extract	1·5 g
Sodium chloride	3·5 g

Sodium chloride	3.5 g
Glucose	1.5 g
Dibasic potassium phosphate	3.68 g
Potassium Dihydrogen Phosphate	1.32 g
Water, sufficient to produce	1,000 ml.

The reaction is adjusted so that the pH is 6·9 to 7·0 after autoclaving.

Instead of preparing the media from the individual ingredients specified, they may be prepared from a dehydrated mixture which, when reconstituted with water, has the specified composition. Minor modifications of the individual ingredients specified are permissible if the resulting media possess growth promoting properties at least equal to the media described.

Preparation of Bulk Culture Suspension

The test organism is Sarcina Lutea (P.C.I.1001 and American Type Culture Collection 9341). The test organism is maintained on slants of nutrient agar as described for the base layer and transferred to a fresh agar slant once a week. A suspension of the test organism is prepared as follows. An agar slant is streaked heavily with the test organism and incubated for 24 hours at 26°C. The growth is washed off with 3·0 ml of nutrient broth. The suspension so obtained is used to inoculate the surface of a Roux bottle containing 300 ml of this nutrient agar. The suspension is spread over the entire surface with the aid of sterile glass-beads. The bottle is incubated for 24 hours at 26°C. Growth is washed from the agar surface with 15 ml of nutrient broth prepared as described. The density of organism in this bulk suspension is tested by diluting 1 part with 9 parts of nutrient broth, and measuring the light transmission at about 650 mu in a suitable photoelectric colorimeter. If the light transmission is about 10% of that of sterile nutrient broth similarly treated, the bulk suspension is satisfactory for use. Otherwise, the bulk suspension is adjusted by dilution so that a 10% dilution of the adjusted suspension gives about 10% light transmission. The bulk suspension, adjusted by dilution if necessary, may be used for at least two weeks.

Preparation of plates

On the day of the assay 10 ml of base layer agarmedium is added to Petri plates (20 mm x 100 mm). The agar is distributed evenly in the plates and allowed to harden.

0·4 ml of bulk culture suspension is added to 100 ml of the agar prepared for the inoculated layer, previously melted and cooled to 48°C. The culture and agar are thoroughly mixed and 4 ml are added to each of the plates containing the 10 ml of the hardened uninoculated agar. The inoculated agar is spread evenly over the surface by tilting the plates back and forth. The plates are covered with procelain covers, glazed on the outside.

Standard curve and assay procedure

Six cylinders are placed on the inoculated agar surface so that they are at approximately 60° intervals on a 2·8 cm redius. One plate is used for each sample. Three cylinders on each plate are filled with the 0·1 ml International Unit per ml dilution of the International Standard Preparation, and three cylinders with the serum sample under test, alternating Standard and sample. The plates are incubated for 16 to 18 hours, at 26°C and the diameter of each zone of inhibition is measured. At the same time, a standard curve is prepared using concentrations of 0·03, 0·05, 0·10, 0·20, 0·30 and 0.40 International Units per ml of the International Standard Preparation in bovine albumin TS. Three plates are used for the determination of each point on the curve making a total of 15 plates. On each of three plates, three cylinders are filled with the 0·1 International Unit per ml dilution of the International Standard Preparation and the other three are filled with one of the five other diluted solutions of the International Standard Preparation. After the plates have been incubated the diameters of the zones of inhibition are read. Thus, there will be 45 determinations at 0·1 International Unit and nine determinations at each of the other points on the curve.

The readings of 0·1 International Unit per ml. concentrations and the readings of the point tested for each set of three plates are averaged and also all 45 readings of the 0·1 International Unit per ml. concentration. The average of the 45 readings of the 0·1 International Unit per ml. concentration is the correction point for the curve. The average value obtained for each point

is corrected to the figure it would be if the 0·1 International Unit per ml. readings for that set of three plates were the same as the correction point. Thus, if the average of the 45 readings of the 0·1 International Unit concentration is 20·0 mm, and the average of 0·1 International Unit concentration of a given set of three plates is 19·8 mm correction is 40·2 mm. If the average reading of the 0·03 International Unit concentration of these same three plates is 17·00 mm, the corrected value becomes 17·2 mm. The corrected value, including the average of the 0·1 International Unit per ml concentration, are plotted on 2 cycle Semi-logarithmic graph paper, using the concentration in International Units per ml. as the ordinate (the logarithmic scale) and the diameter of the zone of inhibition as the abscissa. The standard curve is drawn through these points. To estimate the concentration of penicillin in the sample, the zone readings of the International Standard and the zone readings of the sample on the 1 plate used are averaged. If the sample gives a larger average zone size than the average of the International Standard the difference between the two averages is added to the 0·1 International Unit zone on the standard curve. If the average sample value is lower than the standard value, the difference between the averages is subtracted from the 0·1 International Unit value on the curve. From the curve are read the concentrations of penicillin, in International Units per ml. corresponding to these corrected average zone sizes.

The reagents and solutions refer to the reagents and solutions included in the Indian Pharmacopoeia."

14. In Schedule K(1) for the existing entries 1 and 5, the following shall respectively be substituted, namely :—

Class of Drugs.	*Extend and conditions of Exemption.*
1. Drugs falling under clause (b) (i) of Section 3 of the Drugs Act, not intended for medicinal use.	All the provisions of Chapter IV of the Act and the Rules thereunder, subject to the conditions that the drug is not sold for medicinal use or for use in the manufacture of medicines and that each container is labelled conspicuously with the words "NOT FOR MEDICINAL USE."
5. Drugs supplied by a registered medical practitioner to his own patient or any drug specified in Schedule C supplied by a registered medical practitioner at the request of another such practitioner if it is specially prepared with reference to the condition and for the use of an individual patient provided the registered medical practitioner is not (a) keeping an open shop or (b) selling across the counter or (c) engaged in the importation, manufacture, distribution or sale of drugs in India to a degree which render him liable to the provisions of Chapter IV of the Act and the rules thereunder.	All the provision of Chapter IV of the Act and the rules thereunder, subject to the condition that, in the case of medicine containing a substance specified in Schedule E(a) the medicine shall be labelled with the name and address of the registered medical practitioner by whom it is supplied; (b) if the medicine is for external application, it shall be labelled with the words "Poison", for "External use only" or, if it is for internal use with the dose; (c) the name of the medicine or ingredients of the preparation and the quantities thereof, the dose prescribed, the name of the patient and the date of supply and the name of the person who gave the prescription shall be entered at the time of supply in register to be maintained for the purpose. (d) the entry in the register shall be given a number and that number shall be entered on the label of the container;

Class of Drugs.	*Extend and conditions of Exemption.*
	(e) the register and the prescriptions if any, on which the medicines are issued, shall be preserved for not less than two years from the date of the last entry in the register or the date of the prescription as the case may be."

(ii) after entry 5, the following entry shall be inserted namely :—

5A. Drugs supplied by a hospital or dispensary maintained or supported by Government or local body or by charity or voluntary subscription.	The provisions of Chapter IV of the Act and the Rules thereunder which require them to be covered by a sale licence, subject to the following conditions; (1) the dispensing and supply of drugs shall be carried out by or under the supervision of a qualified person; (2) the premises where drugs are supplied or stocked shall be open to inspection by an Inspector appointed under the Drugs Act who can, if necessary, take samples for test; (3) the drugs shall be stored under proper storage conditions;

(iii) after entry 11, the following entry shall be inserted, namely :—

"12. Insecticides and formulations of insecticides.	The provisions of Chapter IV of the Act and the Rules thereunder which require them to be covered by a sale licence."

15. In item 6 of Schedule L, for the word "Magnamycin" the word "Carbomycin" shall be substituted.".

[No. F. 1-22/59-D.]

M. K. KUTTY, Dy. Secy.

New Delhi, the 3rd May 1960

S.O. 1197.—In exercise of the powers conferred by clause (p) of sub-section (1) of section 6 of the Indian Ports Act, 1908 (15 of 1908), the Central Government hereby makes the following further amendment to the Indian Port Health Rules, 1955, the same having been previously published as required by sub-section (2) of that section, namely:—

In the said Rules, in sub-rule (1) of rule 83 for the words "any ship" the words "any ship or vessel" and for the words "on the vessel" the words "on the ship or vessel" shall be substituted.

[No. F. 15-4/59-IH.]

T. V. ANANTANARAYANAN, Under Secy.

MINISTRY OF TRANSPORT AND COMMUNICATIONS

(Department of Transport)

(Transport Wing)

PORTS

New Delhi, the 3rd May 1960

S.O. 1198.—In pursuance of sub-section (3) of section 6 of the Bombay Port Trust Act, 1879 (Bombay Act VI of 1879), the Central Government hereby publishes the following return received from the Secretary, The Millowners' Association, Bombay, namely:—

Return showing the name of the person elected by the Millowners' Association, Bombay in accordance with the provisions of Section 13(2) of the Bombay Port Trust Act, to be a member of the Board of Trustees