GOVERNMENT OF INDIA

MINISTRY OF HEALTH

AGENDA AND MINUTES OF THE FIFTEENTH MEETING OF THE DRUGS TECHNICAL ADVISORY BOARD

PRINTED IN INDIA BY THE MANAGER,
GOVT. OF INDIA PRESS, NASIK ROAD, 1959

AGENDA FOR THE FIFTEENTH MEETING OF THE DRUGS TECHNICAL ADVISORY BOARD HELD ON 19TH OCTOBER, 1954

I. Confirmation of the minutes of the fourteenth meeting (Dr. K. K. Sen Gupta's comments are at Enclosure A).

II. Consideration of the following points arising from the proceedings of the fourteenth meeting :—

(1) *Item II* (2).—Provisional standards for preparations of crude liver extract for parenteral use. (Enclosure B.)

(2) *Item XI* (2).—Changes in Schedule F to the Drugs Rules, 1945, consequent on the recommendations of the sub-committee.

III. To consider the following communications received from the Government of India:—

(1) (*a*) *Letter No. F.* 1-10/53-DS, *dated the* 11*th December,* 1953.—Amendment of Rule 74 of the Drugs Rules, 1945. (Enclosure C.)

(*b*) *Letter No. F.* 1-10/53-*DS. dated the* 12*th February,* 1954.—Amendment of Rule 74 of the Drugs Rules, 1945. (Enclosure D.)

(2) *Letter No. F.* 1-7/54-*DS, dated the* 7*th May,* 1954.—Exemption in respect of toilet soaps, tooth-pastes etc., under Schedules D and K of the Drugs Rules, 1945. (Enclosure E.)

(3) *Letter No. F.* 1-20/53-*DS, dated* 19*th December,* 1953.—Qualifications for appointment as Drugs Inspector under the Drugs Act, 1940—Delegation of Membership of the Pharmaceutical Society of Great Britain. (Enclosure F.)

(4) *Letter No. F.* 1-1/51-*DS, dated* 24*th June,* 1954.—Amendment to the Drugs Rules, 1945—the words "Product" and "products" to be substituted by the words "drug" & "drugs" respectively. (Enclosure G.)

(5) *Letter No. F.* 1-17/54-*DS, dated the* 19*th July,* 1954.—Amendment to rule 65 (5) of and deletion of Rule 65(8) from the Drugs Rules, 1945. (Enclosure H.)

(6) *Letter No. F.* 1-21/54-*DS, dated the* 25*th August,* 1954.—Amendment to item 5 of Schedule K (Enclosure I.)

IV. To examine what excess unitage should be added to allow for deterioration of potency of sera and anti-toxins on storage.

V. To consider the question whether house-hold remedies like soda-bicarb, soda mint, anacin etc. should be allowed to be sold by unlicensed dealers.

VI. To consider the question whether control over the manufacture of Kahn's antigens and other similar products should be exercised or not.

VII. To consider letter No. D.F./XIV-15/11512, dated 13-8-54 from the Director of Medical & Health Services, U.P. Lucknow. (Enclosure J.)

VIII. To consider the question whether from the entry "Para-aminobenzenesulphonamide; its salts; derivatives....." in Schedule H to the Drugs Rules, 1945, the excluding entry "preparations and dressings containing these for external use" should be so amplified as to cover eye drops, ear drops, nasal drops and pessaries within it.

IX. Any other business allowed by the Chairman.

ENCLOSURE A

COPY OF LETTER DATED THE 26TH MARCH, 1954, FROM DR. K. K. SEN GUPTA, CALCUTTA TO THE SECRETARY, DRUGS TECHNICAL ADVISORY BOARD.

I have received the Minutes of the 14th Meeting of D.T.A.B. under your letter No. 9-6/53-DAB dated 31-10-53.

Please refer to Item No. III (6) page 3 and note that the Minutes should be amended as follows:—

"The Board agreed to the proposed amendment, Shri S. P. Sen and Dr. K. K. Sen Gupta dissenting", for I recorded my dissent in the Meeting.

ENCLOSURE B

PROVISIONAL STANDARDS FOR STANDARDISATION OF CRUDE LIVER EXTRACT PREPARATIONS (INJECTIONS)

I. Physical tests:

(1) *pH.*—As far as possible neutral and in no case should the preparation have an acidity greater than that corresponding to pH_5.

(2) *Total Solids.*—Total solids as determined in accordance with the method laid down in N. F. IX should be not less than 15%.

II. Chemical test:

(1) *Limits of proteins.*—The protein nitrogen, as determined by the method given below, should not exceed 0.08%. To 2 cc of the liver extract sample are added 2 cc of 20% trichloracetic acid making a final concentration of 10% trichloracetic acid. The resulting precipitate is filtered on a filter paper and washed well with 10% trichloracetic acid. The residue along with the filter paper (ash free) is digested and the protein nitrogen estimated by the usual micro-Kjeldal method.

III. Pharmacological tests:

Biological tests for liver injection (crude)

(1) *Test for undue toxicity.*—This is tested in normal white mice weighing between 17 and 22 gm. Intraperitoneal injection of the sample in dosage of 0.25 cc per 20 gm. of mouse does not cause death of any of the five mice tested within a period of 120 hours; if any of the 5 mice dies, the test is repeated and the sample complies with the test if none of the second group of 5 mice dies within 120 hours.

N.B.—Normally period of observation for acute toxicity is 2 hours. If the period is extended to 120 hours, death may be due to other causes.

(2) *Pyrogen test.*—Liver extracts should also be tested for absence of pyrogens. This is tested in normal healthy rabbits weighing between 1.5 and 2.0 kg. Intravenous injection of the sample in 3 rabbits in dosage of 0.5 cc. per kg. does not cause an average maximum rise of rectal temperature above 0·6°C. from the mean initial temperature during the 3 hours following the injection, the temperature being recorded hourly. If the average maximum rise of temperature is above 0.6°C., the test is repeated in 5 other normal rabbits and the sample complies with the test if not more than one of the 5 rabbits tested shows an individual rise in temperature of 0:6°C or more above the initial mean temperature.

(3) *Sterility test.*—The usual sterility test should be performed.

IV. Potency Test :

The potency of liver extract should be assayed in terms of its vitamin B_{12} content which should be determined by the microbiological method using L. Leichmanii 313. The accuracy of the test depends upon the purity of the reference standard employed and that highly purified crystalline vitamin B_{12} triturated with Mannitol 1 in 1,000 should be used as the standard solution.

Method of micro-biological assay of Vitamin B_{12} in Liver preparations

The principle of this method is to determine the influence of vitamin B_{12} on the growth activity of L. Leichmanii 313 as measured by some suitable method.

Culture.—The culture is maintained in a liquid medium composed of skimmed milk, yeast extract and tomato juice weekly subcultures are maintained in refrigerator after an 18 hours incubation at 37°C.

Before the actual assay is undertaken, the microorganism is subcultured on a solid medium composed of Peptone, purified liver powder, Tween 80, glucose and tomato juice. Cultures not more than 48 hours old are used for inoculum.

The inoculum is prepared by suspending the agar washing in sterile normal saline, centrifuging and withdrawing supernatant 2 or 3 times before resuspending in saline to an opacity of No. 2-3 Brown's tubes.

Standard cyanocobalamin solution—This is made from pure crystalline Vitamin B_{12} so that the final concentration is 1 mg per ml.

Test.—Into series of test tubes (6″ × ¾″ specially cleaned and sterile) add 0, 0·5, 1·0, 1·5, 2.10, 2·5, 3·0, 3·5, 4·0, 4·5 and 5·0 ml. of the Standard cyanocobalmine solution and add 5·0 ml. of basal medium*. Make total volume to 10 ml. with distilled water. Similar set for the sample is arranged with suitable dilutions of the sample.

One drop of the inoculum is added to each tube and the sets are incubated at 37°C for 16 to 18 hours, after a mild shaking. The tube without vitamin B_{12} serves as a blank or control. After the incubation, the growth which is graded is measured either by a spectro-photometric device or titrated against an alkali. The figures are plotted on a graph paper and the figures for the sample calculated by interpolation against the figures of the standard.

**Basal Medium Composition*

Acid hydrolysed casein solution	25	ml.
Cystein—Tryptophane solution	25	,,
Tomato juice	50	,,
Aspargine solution	5	,,
Adenine—Guanine uracil solution	5	,,
Xanthene solution	5	,,
Riboflaving Biotin Thiamine—Nicotinic acid solution	10	,,
P-aminobenzoic acid—Ca-pantothenate pyridoxine pyridoxal—pyridoxamine—Folic acid solution	10	,,
Salt solution A	5	,,
Salt Solution B	5	,,
Dextrose (anhydrous)	10	gms.
Sodium acetate (anhydrous)	5	,,
Ascorbic acid	1	gm.
Aqua distilled add up to pH adjusted to 6.8	250	ml.

N. B.—For further details of the method described above the Third supplement to U.S.P. XIV may be consulted.

Storage.—Liver injections should be stored in a cool place (preferably not above 20°C) and protected from light.

Labelling.—Liver extracts should be labelled with the following particulars : —

(1) The potency expressed in terms of vitamin B_{12} content which should not be less than 2 micrograms in a single recommended dose.

(2) The amount of raw liver that has been processed to produce 1 cc. of the extract.

(3) Date of manufacture of the preparation.

(4) A date of expiry of potency which should be not more than 18 months from the date of manufacture.

ENCLOSURE C

No. F. 1-10/53-DS

GOVERNMENT OF INDIA

MINISTRY OF HEALTH

New Delhi-2, the 11th December, 1953.

FROM

Shri Krishna Bihari, M. A.,
Under Secretary to the Government of India.

To

The Secretary,
Drugs Technical Advisory Board,
NEW DELHI.

SUBJECT :—*Drugs Rules,* 1945—*Amendment of Rule* 74 *of the.*

SIR,

I am directed to refer to this Ministry's endorsement No. F. 1-10/53-DS. dated the 9th June 1953, and to say that all Part A State Governments have agreed to the proposed amendment to the Drugs Rules with the exception of the Government of Bombay who have suggested some modifications to the draft amendments. A copy of letter No. DRG. 1053/33288-H, dated the 16th November, 1953, with enclosure, from the Government of Bombay is enclosed. I am to request that the proposed amendment to the Central and State Drugs Rules and the letter received from the Government of Bombay may be placed for consideration before the Drugs Technical Advisory Board at their next meeting on behalf of the Central and State Governments and the views of the Board communicated to this Ministry.

Yours faithfully,
(Sd.) K. BIHARI,
Under Secretary.

COPY OF LETTER NO. F. 1-10/53-DS, DATED THE 9TH JUNE, 1953 FROM THE UNDER SECRETARY TO THE GOVERNMENT OF INDIA, MINISTRY OF HEALTH, NEW DELHI, TO ALL PART A STATE GOVERNMENTS.

SUBJECT :—*Drugs Rules*, 1945—*Amendment of Rule* 74 *of the*.

SIR,

I am directed to invite your attention to discussion on item 1(ii) of the Agenda in the minutes of the Second Meeting of the Drugs Consultative Committee (copy forwarded to the State Government with this Ministry's letter No. D. 1973-DS/52, dated the 28th November, 1952). The Government of India have accepted the recommendations of the Drugs Consultative Committee and propose to amend Rule 74 of the Drugs Rules as in the attached draft notification after consulting the Drugs Technical Advisory Board.

2. I am to enquire whether the State Government agree to the Board being consulted for the purpose of amending the State Drugs Rules on the same lines. If the State Government agree, the Central Government will consult the Board on behalf of itself and the State Government and communicate to the State Government the views of the Board. Further action for the amendment of the Central and State Drugs Rules can be taken after the view of the Board are received.

No. F. 1-10/53-DS.

Copy with enclosure forwarded to the Director General of Health Services for information with reference to his U.O. No. 7/6/52-DC dated the 29th December, 1952.

By Order,

(Sd.) S. DEVANATH,

Under Secretary.

Draft Amendment

For rule 74 of the said Rules the following rules shall be substituted, namely:—

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

(a) the licensee shall provide and maintain adequate premises, staff and plant for the proper manufacture and storage of the substances in respect of which the licence is issued;

(b) the licensee shall either—

(i) provide and maintain adequate premises and plant for carrying out the required tests of the strength, quality and purity of the products manufactured, 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;

(c) the licensee shall keep records for the details of manufacture of each batch of the substance which is issued for sale and of the application of the tests thereto in such forms to be available for inspection and to be easily identified by reference to the number of the batch as shown on the label of the container and such records shall be retained for a period of ten years;

(d) the licensee shall allow any Inspector authorised by the licensing authority in that behalf to enter, with or without giving notice, any premises where the manufacture is carried on and to inspect the plant and the process of manufacture and the means applied for standardising and testing of the substance;

(e) the licensee shall allow an Inspector authorised by the licensing authority to inspect all registers and records maintained under these rules and to take samples of the manufactured product and shall supply to the Inspector such information as he may require for the purpose of ascertaining whether the provisions of the Act and Rules thereunder have been observed;

(f) the licensee shall from time to time report to the licensing authority any changes in the expert staff responsible for the manufacture or testing of the substance and any material alterations in the premises or plant used for that purpose which have been made since the date of the last inspection made on behalf of the licensing authority before the issue of license;

(g) the licensee shall on request furnish to the licensing authority or such other authority as the licensing authority may direct from every batch of the substance, or from such batch or batches as the licensing authority may from time to time specify, a sample of such amount as the authority may consider adequate for any examination required to be made and the licensee shall, if so required, furnish full protocols of the tests which have been applied;

(h) if the licensing authority so directs, the licensee shall not sell or offer for sale any batch in respect of which a sample is drawn, or protocols are furnished under the last preceding sub-paragraph, until a certificate authorizing the sale of the batch has been issued to him by or on behalf of the licensing authority;

(i) the licensee shall, on being informed by the licensing authority that any part of any batch of the substance has been found by the licensing authority not to conform with the standards of strength, quality or purity specified in these rules, and on being directed so to do, withdraw the remainder of that batch from sale and so far as may in the particular circumstances of the case be practicable, recall all issues already made from that batch;

(j) no drug manufactured under the licence shall be sold unless the precautions necessary for preserving its properties have been observed throughout the period after manufacture;

(k) 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 in any Rules subsequently made under Chapter IV of the Act, of which the licensing authority has given the licensee not less than four month's notice".

(Sd.) S. DEVANATH,

Under Secretary.

COPY OF LETTER NO. DRG. 1053/33288-H, DATED THE 16TH NOVEMBER, 1953 FROM THE GOVERNMENT OF BOMBAY TO THE MINISTRY OF HEALTH, NEW DELHI.

SUBJECT :—*Drugs Rules,* 1945—*Amendment of Rule* 74 *of the.*

I am directed to refer to Shri S. Devanath's letter No. F. 1-10/53-DS dated the 9th June 1953 on the subject mentioned above, and in forwarding herewith a copy of letter from the Drugs Controller for the State of Bombay No. DC. I/7354, dated 8th September, 1953, I am to state that this Government concurs in the view expressed by him. The State Government also agrees to the Drugs Technical Advisory Board being consulted in the matter subject to the remarks made by the Drugs Controller in his letter referred to above.

I am to request that the views of the Board may kindly be communicated to the State Government in due course.

COPY OF LETTER NO. D.C./1/7354 DATED 8TH SEPTEMBER, 1953 FROM THE DRUGS CONTROLLER FOR THE STATE OF BOMBAY.

SUBJECT :—*Drugs Rules,* 1945—*Amendment to Rule* 74 *of the.*

With reference to your endorsement No. S. 228/45629-G dated 20-6-1953 on the subject mentioned above, I have the honour to state that I agree with the proposed draft Notification substituting the existing Rule 74 of the Drugs Rules, 1945 by the one proposed in the draft amendment, subject to the following remarks :—

(1) In condition (a) :—

(i) the word "Licence" should be substituted by the word "Licensee",

(ii) the word "substances" should be replaced by the word "drugs".

(2) In condition (b), under sub-clause (i) the word "plant" occurring in the first line thereof, should be replaced by the word "equipment" as for testing purposes what is necessary is "equipment" and not the "plant".

(3) In condition (c), at the end of the third line the word "as" should be inserted between the words "forms" and "to be".

(4) In condition (e) the word "manufacture" at the beginning of the 4th line, should be corrected as "manufactured".

(5) After condition (k) the following additional condition should be added as condition (1) :—

"(1) the licensee shall, if demanded by a dealer, furnish a warranty either in form 22 or form 23".

This additional condition is necessary and was already proposed earlier in 1951 in the draft Notification accompanying Government of India, Ministry of Health letter No. F. 1-18/51-DS dated 17-11-1951 a copy of which was forwarded to this office for remarks under your endorsement No. S. 228/76568-G dated 17-12-1951, but presumably it has not been published finally.

As a result of the amendments to Rule 74 suggested above, some consequential amendments to Rule 78 become necessary which may also be considered in consultation with the Drugs Technical Advisory Board.

ENCLOSURE D

COPY OF LETTER NO. F.1-10/53-D.S., DATED THE 12TH FEBRUARY, 1954, FROM THE UNDER SECRETARY TO THE GOVERNMENT OF INDIA, MINISTRY OF HEALTH, NEW DELHI TO THE SECRETARY, DRUGS TECHNICAL ADVISORY BOARD, NEW DELHI.

SUBJECT :—*Drugs Rules,* 1945—*Amendment of Rule* 74 *of the.*

In continuation of this Ministry's letter No. F. 1-10/53-D.S. dated the 11th December, 1953, I am directed to forward herewith a copy of a letter No. DRG. 1053/43978-H, dated the 8th January, 1954, with enclosure, from the Government of Bombay to be placed for consideration before the Drugs Technical Advisory Board at its next meeting along with the original proposal.

COPY OF LETTER NO. DRG. 1053/43978-H, DATED THE 8TH JANUARY, 1954, FROM THE SECRETARY TO THE GOVERNMENT OF BOMBAY, LOCAL SELF GOVERNMENT AND PUBLIC HEALTH DEPARTMENT, BOMBAY, TO THE SECRETARY TO THE GOVERNMENT OF INDIA, MINISTRY OF HEALTH, NEW DELHI-2.

In continuation of this Department letter No. DRG. 1053/33288-H. dated the 16th November, 1953 on the subject mentioned above, I am directed to forward herewith a copy of letter from the Drugs Controller for the State of Bombay No. DCI/7355 dated the 8th September, 1953, which relates to an amendment to form No. 25 under rule 74 of the Drugs Rules 1945. I am to state that the Government of Bombay concurs in the views expressed by the Drugs Controller.

2. I am to request that the matter may be placed before the Drugs Technical Advisory Board and its views may kindly be communicated to the State Government in due course.

COPY OF LETTER NO. D.C./1/7355 OF 1953, DATED THE 8TH SEPTEMBER, 1953, FROM THE DRUGS CONTROLLER FOR THE STATE OF BOMBAY TO THE SURGEON GENERAL WITH THE GOVERNMENT OF BOMBAY, BOMBAY-1.

SUBJECT :—*Drugs Rules,* 1945—*Amendments to Form* 25.

In continuation of this Office letter No. D.C./1/7354 dated the 8th September 1953, in which the amendment to rule 74 were suggested, I have the honour to state that since the conditions as proposed under rule 74 directly govern the licences issued in Form 25, the existing Form 25 would, in my opinion, also require amendments to make the control effective in all respects. I, therefore, suggest the following amendment to Form 25 :—

(1) Under Schedule A to the Drugs Rules 1945—

(i) In Form 25, para 1 should be substituted by the following para :—

.....is hereby licensed to manufacture at the premises situated at the following drugs, being drugs other than drugs specified in schedules C and C(1) to the Drugs Rules, 1945 :—

Name of drugs :—

(2) The following new para should be added as para 2 :—

"2. Names of approved expert staff. .....".

(3) The existing paras 2, 3 and 4 should be renumbered as paras 3, 4 and 5.

(4) Under "Conditions" of Form 25, the following new condition should be added as condition No. 3:—

"3. If the licensee wishes to undertake during the currency of the licence the manufacture of any drug other than drug specified in Schedules C and C(1) not included above, he should apply to the licensing authority for permission to manufacture the drug. This licence will be deemed to authorise the manufacture of any drug in respect of which such permission has been given".

It is requested that the State Government may be advised to approach Government of India to consult the Drugs Technical Advisory Board. The amendments proposed above will have to be considered along with the amendment to rule 74.

ENCLOSURE E

No. F. 1-7/54-DS

GOVERNMENT OF INDIA

MINISTRY OF HEALTH

New Delhi-2, dated 7th May, 1954.

FROM

Shri Krishna Bihari, M. A.,
Under Secretary to the Government of India.

To

The Secretary,
Drugs Technical Advisory Board,
New Delhi.

SUBJECT :—*Amendment of the Drugs Rules,* 1945-*Examination in respect of toilet soaps, tooth-paste etc. under Schedules D and K of the Drugs Rules.*

SIR,

I am directed to say that the question as to whether toilet soaps, tooth-pastes etc. claiming to have medicinal properties should be controlled under the Drugs Act, 1940 has been under the consideration for the Government of India for some time. It has been suggested that instead of specifically exempting such items from the definition of the term "drug" in the Drugs Act, necessary exemptions in this respect should be provided under Schedules D and K to the Drugs Rules. I am to request that the matter may be placed for consideration before the Drugs Technical Advisory Board and its views communicated to this Ministry in due course.

Yours faithfully,
(Sd.) K. BIHARI,
Under Secretary.

ENCLOSURE F

No. F. 1-20/53-DS

GOVERNMENT OF INDIA

MINISTRY OF HEALTH

New Delhi-2, Dated 19th December, 1953.

FROM

Shri Krishna Bihari, M.A.,
Under Secretary to the Government of India.

To

All Part A State Governments (including Andhra).

SUBJECT :—*Drugs Rules,* 1945—*Qualifications for appointment as Drugs Inspector under the Drugs Act,* 1940—*Deletion of membership of the Pharmaceutical Society of Great Britain.*

SIR,

I am directed to say that in accordance with rule 49(b) of the Drugs Rules, 1945, membership of the Pharmaceutical Society of Great Britain is one of the qualifications for appointment as a Drugs Inspector under the Drugs Act, 1940. The Pharmaceutical Society of Great Britain used to give the following two diplomas:—

1. Chemist and Druggist; and

2. Pharmaceutical Chemist.

Holders of both the diplomas were entitled to be designated as Members of the Pharmaceutical Society (M.P.S.). The Chemist & Druggist diploma has a lower status as compared to the Pharmaceutical Chemist's diploma, the latter being more or less equal to the B. Pharm. degree. As the Pharmaceutical Chemist's diploma granted by the Pharmaceutical Society of Great Britain has already been included among the qualifications for appointment as Drugs Inspectors under the Drugs Act, 1940 [*vide* clause (aa) of rule 49 of the Drugs Rules, 1945], it is considered that there is no need to retain membership of the Pharmaceutical Society of Great Britain among the qualifications required for appointment as Drugs Inspectors and that clause (b) of rule 49 of the Drugs Rules, 1945 should consequently be deleted.

2. I am to enquire whether the State Government agree to the Drugs Technical Advisory Board being consulted for the purpose of amending the State Drugs Rules on the same lines. If the State Government agree, the Central Government will consult the Drugs Technical Advisory Board, on behalf of itself and the State Government, and communicate to the State Government the views of the Board. Further action for the amendment of the Central and State Rules can be taken after the views of the Board are obtained. The favour of an early reply is requested.

Yours faithfully,
(Sd.) X X X
Under Secretary.

No. F. 1-20/53-DS

GOVERNMENT OF INDIA

MINISTRY OF HEALTH

New Delhi-2, dated 17th June, 1954.

FROM

Shri Krishna Bihari M. A.,
Under Secretary to the Government of India.

To

The Secretary,
Drugs Technical Advisory Board,
C/o Director General of Health Services,
New Delhi.

SUBJECT:—*Drugs Rules,* 1945. *Qualifications for appointment as Drugs Inspector under the Drugs Act* 1940—*Deletion of Membership of the Pharmaceutical Society of great Britain.*

SIR,

I am directed to refer to this Ministry's endorsement No. F. 1-20/53-DS, dated the 19th December, 1953, and to say that all Part A State Governments have agreed to the proposed amendment to the Drugs Rules. I am to request that the proposed amendment to the Central and State Drugs Rules may be placed for consideration before the Drugs Technical Advisory Board at their next meeting on behalf of the Central and State Governments and the views of the Board communicated to this Ministry.

Your faithfully,
(Sd.) K. BIHARI,
Under Secretary.

ENCLOSURE G

No. F. 1-1/51-DS

GOVERNMENT OF INDIA

MINISTRY OF HEALTH

New Delhi-2, the 24th June, 1954.

FROM

Shri Krishna Bihari, M. A.,
Under Secretary to the Government of India.

To

The Secretary,
Drugs Technical Advisory Board,
Directorate General of Health Services,
New Delhi.

SUBJECT :—*Drugs Rules,* 1945—*Amendments to.*

SIR,

I am directed to forward herewith a copy of this Ministry's letter No. F. 1-1/51-DS, dated the 4th September, 1953, (with enclosure) and to say that all Part A State Governments have agreed to the proposal. The Government of Orissa have, however, made certain comments *vide* their letter No.

1336-H, dated the 26th February, 1954. A copy each of the Orissa Government's letter and this Ministry's reply thereto (letter No. F. 1-1/51-DS, dated the 31st May, 1954) are enclosed. I am to request that the proposed amendments to the Drugs Rules may kindly be placed before the Drugs Technical Advisory Board at its next meeting and the views of the Board communicated to this Ministry in due course.

Yours faithfully,
(Sd.) K. BIHARI,
Under Secretary.

A COPY OF LETTER NO. F. 1-1/51-DS, DATED THE 4TH SEPTEMBER 1953 FROM GOVERNMENT OF INDIA, MINISTRY OF HEALTH TO ALL PART A STATE GOVERNMENTS.

SUBJECT :—*Drugs Rules,* 1945—*Amendments to.*

I am directed to say that the Government of India are of opinion that the words 'product' and 'products' wherever they occur in the Drugs Act and Rules should be substituted by the words 'drug' and 'drugs' respectively. A list of the detailed amendments to the Schedule to Drugs Act, 1940, to the Central Drugs Rules, 1945, and to the Schedules to them which will become necessary is attached. It is proposed to consult the Drugs Technical Advisory Board regarding these amendment.

I am to enquire whether the State Government agree to the Board being consulted for the purpose of amending the schedule to the Drugs Act, 1940 and the State Drugs Rules on the same lines. If the State Government agree, the Central Government will consult the Board on behalf of itself and the State Government and communicate the State Government the views of the Board. Further action for the amendment of the Schedule to the Act and the Central and State Drugs Rules can be taken after the views of the Board are received.

For the word 'product' the word 'drug' shall be substituted in the following Rules of the Drugs Rules, 1945 :—

Rule 23
Rule 30
Rule 31
Rule 52(2)
Rule 74(c)
Rule 109(3) (a)

For the word 'products' the word 'drugs' shall be substituted in the Schedule to the Drugs Act, 1940, and the following Rules and Schedules to the Drugs Rules, 1945 :—

Item 2 of the Schedule to the Drugs Act.
Item 3 of the Schedule to the Drugs Act.
Rule 52(2)
Rule 62-A
Rule 64
Rule 69

Rule 70
Heading of Part X
Rule 109 (3) (b)

Schedule A to the Drugs Rules—Form 9.
Schedule A to the Drugs Rules—Form 10.
Schedule A to the Drugs Rules—Form 19.
Schedule A to the Drugs Rules—Form 19-A.
Schedule A to the Drugs Rules—Form 20.
Schedule A to the Drugs Rules—Form 20-A.
Schedule A to the Drugs Rules—Form 21.
Schedule A to the Drugs Rules—Form 21-A.
Schedule A to the Drugs Rules—Form 24.
Schedule A to the Drugs Rules—Form 25.
Schedule A to the Drugs Rules—Form 27.
Schedule A to the Drugs Rules—Form 28.
Schedule C to the Drugs Rules.
Schedule C(1) to the Drugs Rules.
Item 2 of Schedule D to the Drugs Rules.
Item 3 of Schedule K to the Drugs Rules.

COPY OF LETTER NO. 1336-H, DATED THE 26TH FEBRUARY, 1954, FROM THE GOVERNMENT OF ORISSA, HEALTH DEPARTMENT, CUTTACK TO THE GOVT. OF INDIA, MINISTRY OF HEALTH, NEW DELHI.

SUBJECT :—*Drugs Rules,* 1945—*Amendments to.*

REFERENCE :—*Your letter No. F.* 1-1/51-*DS, dated the* 4-9-1953.

I am directed to say that though on Principle the State Government would have no objection to the proposal for the Government of India consulting on behalf of the State Government the Drugs Technical Advisory Board for the purpose of amending the Schedule as indicated in your letter under reply, the State Government would bring the following points to the notice of the Government of India for clarification.

It is not clear as to why the word 'products' is proposed to be substituted by the word 'drugs' wherever the same occurs in the above-mentioned Act and Rules thereunder. Furthermore, the words do not have the same meaning in all cases, as all drugs may be final products but all products are not drugs.

In the light of the above the amendment proposed by the Government of India is not clear in respect of the following items :—

Rule 109 (3) :

(a) the name and address of the manufacturer of the final drug (in place of products).

Form 25 :

Licence to manufacture drugs other than biological and special drugs (in place of products).

A very early reply in the matter will be appreciated.

COPY OF LETTER NO. F.1-1/51-DS. DATED THE 31ST MAY, 1954, FROM THE GOVERNMENT OF INDIA, MINISTRY OF HEALTH, NEW DELHI TO THE SECRETARY TO THE GOVERNMENT OF ORISSA, HEALTH DEPARTMENT, CUTTACK.

SUBJECT :—*Drugs Rules,* 1945—*Amendments.*

I am directed to refer to your letter No. 1336-H, dated the 26th February, 1954, on the subject mentioned above and to say that in rule 23 of the Drugs Rules, 1945 the words "any biological or other special product" have been used. In Schedule C or C(1) also the word "product" has been used. So long as the word "product" remains in the main rule it is not proper to use the word "drug" in the proviso to that rules to mean the same thing. It is , therefore, considered that uniformity of expression as well as uniformity of import should be observed in drafting as far as practicable. In view of this the Government of India are of opinion that the words 'product' and 'products' wherever they occur in the Drugs Act and Rules should be substituted by the words 'drug' and 'drugs' respectively.

ENCLOSURE H

No. F. 1-17/54-DS

GOVERNMENT OF INDIA

MINISTRY OF HEALTH

New Delhi, the 19*th July,* 1954.

FROM

Shri Krishna Bihari, M. A.,
Under Secretary to the Govt. of India.

TO

All Part A State Governments (including Andhra).

SUBJECT :—*Drugs Rules,* 1945—*Amendments to Rule* 65 (5) *and deletion of sub-rule* (8) *regarding maintenance of records.*

SIR,

I am directed to refer to your reply to this Ministry's letter No. F. 1-20/49-DS, dated the 25th June, 1952 and to say that the question whether it is necessary to amend rule 65(5) of the Drugs Rules with a view to making it incumbent on all persons or firms engaged in the wholesale dealing of drugs to maintain separate registers for the purpose of the said sub-rule has been re-examined by the Government of India in the light of the decision given by the Punjab High Court in a case under the Drugs Act, 1940. It has been ruled by the Punjab High Court in this particular case that since cash invoices are considered as registers for the purpose of Sales-tax and the Income Tax Acts, no other separate records need be maintained in pursuance of the provision of rule 65(8) of the Drugs Rules, 1945. It is, therefore, considered that sub-rule (8) of Rule 65 should be deleted and the amendment originally proposed (*vide* this Ministry's letter No. F. 1-20/49-DS, dated the 10th February, 1950) should be made with a slight modification. The Government of India in this connection propose to make amendments in the Central Drugs Rules, 1945 as indicated in the attached draft notification.

2. I am to enquire whether the State Government agree to the Drugs Technical Advisory Board being consulted for the purpose of amending the State Drugs Rules on the same lines. If the State Government agree, the Central Government will consult the Drugs Technical Advisory Board on behalf of itself and the State Government and communicate to the State Government the views of the Board. Further action for the amendment of the Central and State Drugs Rules can be taken after the views of the Board are obtained.

Yours faithfully,
(Sd.) K. BIHARI,
Under Secretary.

No. F. 1-17/54-DS

Copy with enclosure forwarded to the Secretary, Drugs Technical Advisory Board for placing the proposed amendments to the Central and State Drugs Rules before the Board at its next meeting on behalf of Central and State Governments concerned and communicating the views of the Board in due course. A further communication will be sent when all the State replies are received.

By Order,
(Sd.) K. BIHARI,
Under Secretary.

Draft Notification

The following draft of a further amendment to the Drugs Rules, 1945, which it is prepared to made in exercise of the powers conferred by section 33 of the Drugs Act, 1940 (XXIII of 1940), is published, as required by the said section for the information of persons likely to be affected thereby and notice is hereby given that the said draft will be taken into consideration after the————.

Any objections or suggestions which may be received from any persons with respect to the said draft before the date specified, will be considered by the Central Government.

Draft Amendment

In rule 65 of the said Rules—

(i) for clause (5), the following clause shall be substituted, namely :—

"(5) All purchases and sales by way of wholesale dealing of drugs, specified in Schedule C shall be recorded in a register or registers which shall include the following particulars, namely :—

(a) the dates of purchase and sale of the drugs;

(b) the names and addresses of the concerns from which the drugs were purchased and the concerns to which they were sold;

(c) the names of the drugs, the quantities and the batch numbers;

(d) the name of the manufacturer.

Such record shall be preserved for three years from the date of the sale of the drugs :

Provided that the licensing authority may allow such other types of records to be maintained as may be considered adequate in his opinion so long as the particulars required by this rule are made available readily at one place in the record"; and

(ii) clause (8) shall be omitted.

ENCLOSURE I

No. F. 1-21/54-DS

GOVERNMENT OF INDIA
MINISTRY OF HEALTH

New Delhi-2, dated the 25th August, 1954.

FROM

Shri Krishna Bihari, M. A.,
Under Secretary to the Govt. of India.

TO

All Part A State Governments.

SUBJECT :—*Drugs Rules,* 1945—*Proposed amendment to item* 5 *of Schedule K.*

SIR,

I am directed to forward herewith a copy of letter No. HL3/7172/54/DD, dated the 8th June, 1954, from the Government of Travancore-Cochin, with enclosure, and to say that it is proposed to refer the matter to the Drugs Technical Advisory Board, I am to enquire whether the State Government agree to the Board being consulted for the purpose of amending the State Drugs Rules on the same lines. Further action regarding the amendment of the Central and State Drugs Rules will be taken after the view of the Board have been received. The favour of an early reply is requested.

Yours faithfully,
(Sd.) K. BIHARI,
Under Secretary.

No. F. 1-21/54-DS

Copy, with a copy of enclosure, forwarded to the Secretary, Drugs Technical Advisory Board, New Delhi, with reference to his u.o. No. 3-15/54-DAB, dated the 17th July, 1954. It is requested that the views of the Board may be obtained in the matter and communicated to this Ministry in due course. The concurrence or views of the State Governments will be communicated as and when received.

Copy forwarded to the Secretary to the Government of Travancore-Cochin, Development Department, Trivandrum for information with reference to Shri Narayana Menon's letter No. HL 3-7172/54/DD, dated the 8th June, 1954. A further communication will follow in due course.

By Order,
(Sd.) K. BIHARI,
Under Secretary

2—1 M. of Health/58 (15th meeting)

COPY OF THE LETTER NO. HL 3-7172/54/DD. DATED THE 8TH JUNE, 1954 FROM THE GOVERNMENT OF TRAVANCORE-COCHIN TO THE GOVERNMENT OF INDIA MINISTRY OF HEALTH.

SUBJECT :—*Drugs Act,* 1940—*Enforcement of the provisions of.*

REFERENCE.—*Your letter No.* 3-2/51-DS, *dated the* 22*nd May,* 1953, *and this Government letter No.* HL3-3577/52/EHL, *dated the* 14*th July,* 1953.

The Travancore-Cochin Drugs Rules have already been finalised without modification as per the draft forwarded to you in this Government's letter cited above. The Rules came into force on 1st December 1953.

2. The State Surgeon General who is also the Drugs Controller has now suggested an amendment to item 5 in Schedule K of the Rules so that the exemption enjoyed by hospitals, dispensaries, Nursing homes etc. run by local body or by charity or voluntary subscription may be taken away. A copy of his letter No. GI-1904/54 dated the 26th March, 1954 on the subject is enclosed. I request that the matter may be placed before the Drugs Technical Advisory Board for their views on the amendment suggested by the Surgeon General and to communicate their advice.

COPY OF LETTER NO. GI-1904/54 DATED 26-3-1954 FROM THE DRUGS CONTROLLER, TRIVANDRUM.

SUBJECT :—*Drugs Act—Enforcement of.*

I would request you to enlighten me on the following:—

Chapter 4 of the Drugs Act 1940 is in force in the T-C State from 1st December 1953. Chapter 4 of the Act and the rules framed thereunder deals with "manufacture, sale and distribution of Drugs". Chapter 4 mainly stipulates the conditions and principles to be followed in the manufacture, sale, storage, etc., of Drugs.

Rule 123 (Chapter XII of the T-C Drugs Rules 1953 make certain exemptions from the provisions of Chapter 4 of the Act in Schedule K, some of which go contrary to the purpose for which the Act is meant regarding section 5 of the Schedule K. The Drugs Act and the rules specify the conditions under which a drug should be stored, the precautions to be adopted in maintaining the potency and quality of the drug, the qualifications and practical experience of the persons who are allowed to dispense the drug, etc. So far as these facts are concerned, the agency under whose auspices the sale, stocking or distribution of the drug is immaterial. The precautions necessary to prevent the deterioration of the potency and quality of a drug (re-storage conditions) has to be strictly followed and the persons directly responsible for the dispensing of the drug should be competent to do that work irrespective of whether a drug is in the custody of a private hospital, dispensary or a retailer. In this connection only the hospitals and dispensaries directly run by the Government (and as such the Surgeon General who is also the Drugs Controller or the Director of Public Health will have control over them) can be expected to follow the rules framed by the Government.

The other institutions whether aided by local body or by charity, voluntary subscriptions, or dispensaries, private hospitals, nursing homes, etc. run by registered medical practitioners, or dispensaries run by factories, estates, etc. should also come under the provisions of the Drug Rules.

ENCLOSURE J

COPY OF LETTER NO. D.F./XIV-15/11512 DATED THE 13TH AUGUST, 1954 FROM COLONEL A. N. CHOPRA, DIRECTORATE OF MEDICAL AND HEALTH SERVICES, UTTAR PRADESH, LUCKNOW, TO THE DIRECTORATE GENERAL OF HEALTH SERVICES, NEW DELHI.

I have the honour to state that at its last meeting the U.P. State Health Council, passed a resolution that "Tinctures etc. which deteriorate on keeping should have printed on their label the date of manufacture so that users may know whether the drug is therapeutically effective or has become useless". The Government of India have already sent a draft notification to amend Rule 122 of the Drugs Rules to the effect that the date of manufacture shall be printed or written in indelible ink on the labels of Schedule C(1) substances, *vide* letter No. F. 1. 3/54-DS, dated New Delhi, 13th February 1954, from the Under Secretary to Government of India, Ministry of Health, to all Part 'A' State Governments. While this draft amendment would cover Tr. Digitalis, Liq. Ext. of Ergot and vitamin preparation Penicillin Lozenges and Ointments etc. and is a move in the right direction, the duration of potency or the date of expiry should also be printed on the labels of these drugs so that the medical profession and the users may know whether any particular item is therapeutically effective or has become inert

In addition there are several drugs other than Schedule C and C (i) *e.g.* Volatile preparations like Spt. Aetheris Nitrosi, Spt. Ammon Arsomat and Hydrogen Peroxide and drugs like Tinctures Belladonna, Hyoscyamus, Stramonium, Asafoetida and Valerian Ammoniata which also deteriorate on keeping. Hence I suggest that the Drugs Rules be so amended as to make it obligatory for the manufacturers to print the date of manufacture as well as the approximate duration of potency on these drugs also which, in my opinion is about one year in the case of the above volatile preparations and one and a half year in the case of these tinctures. Further Tr. Digitalis, Liq. Ext. Ergot and volatile preparations should be packed in small sized *i.e.,* 4 oz. containers, so that they may be quickly consumed thus avoiding the deleterious effects of air and light on their potency in the dispensing shelf of a hospital or chemists shop, when packed in pound bottles.

MINUTES OF THE FIFTEENTH MEETING OF THE DRUGS TECHNICAL ADVISORY BOARD HELD ON THE 19TH OCTOBER, 1954

Present :

1. Lt. Col. C. K. LAKSHMANAN, Director General of Health Services (*Chairman*).
2. Lt. Col. M. L. AHUJA, Director, Central Research Institute, Kasauli.
3. Dr. M. D. CHAKRAVARTI, Director, Central Drugs Laboratory, Calcutta.
4. Dr. B. N. GHOSH, Carmichael Medical College, Calcutta.
5. Dr. M. L. GUJRAL, Professor of Pharmacology, Medical College, Lucknow.
6. Dr. J. C. GUPTA, 2 Chandranath Chatterji Street, Calcutta 25.
7. Dr. B. D. KOCHHAR, Public Analyst, Punjab Government, Ambala Cantt.
8. Shri P. S. KRISHNAN, Chief Chemist, Central Revenues Control Laboratories, New Delhi.
9. Dr. H. R. NANJI, Managing Director, ITALAB LTD., Fort, Bombay.
10. Shri S. NARAYANA IYER, Government Analyst (Food & Drugs), King Institute, Guindy, Madras.
11. Dr. J. N. RAY, Sea Face Hotel. Marine Drive, Bombay.
12. Dr. K. K. SEN GUPTA, 45-1-B, Beadon Street, Calcutta 6.
13. Shri P. M. NABAR, Drugs Controller (India), Directorate General of Health Services, New Delhi—(*Member and Secretary*).

Apologies for absence were received from Shri S. P. Sen and Dr. P. K. Ghosh.

At the outset, the Chairman welcomed Dr. Gujral and other new members of the Board and thanked all the members for having made it possible to attend the meeting.

Item I of the Agenda—Confirmation of the Minutes of the Fourteenth Meeting

The minutes were confirmed subject to Item No. III(6) of the minutes being amended to read :—

"The Board agreed to the proposed amendment, Shri S. P. Sen and Dr. K. K. Sen Gupta dissenting."

Item II of the Agenda—Consideration of the following points arising from the Proceedings of the Fourteenth Meeting

(1) *Item II*(2).—Provisional standards for preparations of crude Liver extract for parenteral use.

The standards for preparations of crude liver extract for parenteral use prepared by the sub-committee were accepted provisionally. The Board desired that, so far as the "Test for undue toxicity" was concerned, a clarification should be obtained from Dr. Mukerji as to whether it would not be adequate if the test was carried out for a period of 72 hours as was done normally and whether it would be necessary to extend the test for a period of 120 hours. Dr. Mukerji's views should be circulated to the members in order to enable the Board to consider the question of accepting the standards finally.

(2) *Item XI* (2).—Changes in Schedule F to the Drugs Rules 1945, consequent on the recommendations of the sub-committee.

The Board agreed to make the following changes in Schedule F to the Drugs Rules:—

In Schedule F to the Drugs Rules, 1945, the words "or any other name approved by the Licensing Authority" shall be added at the end in the definition of proper names under

(1) Carbolised Antirabic Vaccine;

(2) Gas-gangrene Antitoxin (Vibrion Septique); and

(3) Insulin.

Item III of Agenda—To consider the following communications received from the Government of India

(a) *Letter No.* F. 1-10/53-DS, *dated* 11-12-53—*Amendment of Rule* 74 *of the Drugs Rules,* 1945.

(b) *Letter No. F.* 1-10-53-*DS, dated* 12-2-54—*Amendment of Rule* 74 *of the Drugs Rules,* 1945.—The Board agreed that the amendment proposed by the Government of India should be made in rule 74. The changes suggested by the Drugs Controller for the State of Bombay, with the exception of the one in respect of condition (c) of the licence, were also accepted.

(2) *Letter No. F.* 1-7/54-DS, *dated* 7-5-54—*Exemption in respect of toilet soaps, tooth-paste etc. under Schedules D and K of the Drugs Rules,* 1945.—The Board recommended that toilet articles which do not claim any medicinal properties should be exempted from the provisions of the Drugs Act and Rules by making suitable amendments in Schedules D and K to the Drugs Rules.

(3) *Letter No. F.* 1-20/53-*DS, dated* 17-6-54—*Qualifications for appointment of Drugs Inspector under the Drugs Act,* 1940.—*Deletion of Membership of the Pharmaceutical Society of Great Britain.*—The Board agreed to the amendment suggested by the Government of India.

(4) *Letter No. F.* 1-1/51-*DS, dated* 24-6-1954—*Amendment to the Drugs Rules,* 1945 *the words "Product" and "Products" to be substituted by the words "drug" and "drugs" respectively.*—The Board considered Government of India's suggestion that the words "Product" and "Products", wherever they occur in the Drugs Act and Rules, should be substituted by the words "Drug" and "Drugs" respectively. The Board felt that pharmacopoeias and

other books connected with drugs generally used the words "substance", "product", "preparation" etc. to denote a drug. Besides, the common practice was to use the term "biological products" instead of "biological drugs". It was also considered that the proposed amendments might not read well in many places such as the one pointed out by the Orissa Government. In view of these reasons, the Board was of opinion that unless there were weighty legal reasons for making the suggested changes, the Drugs Rules should be allowed to continue in their present form.

(5) *Letter No. F.* 1-17/54-*DS, dated* 24-6-54—*Amendment to rule* 65(5) *of any deletion of rule* 65(8) *from the Drugs Rules,* 1945.—The Board agreed to the changes suggested in rule 65(5) subject to the condition that the provision "Such record shall be preserved for three years from the date of sale of the drugs" was brought at the end of the proviso. The deletion of clause (8) of Rule 65 was also agreed to.

(6) *Letter No. F.* 1-21/51-*DS, dated* 25-8-54—*Amendment to Item* 5 *of Schedule K.*—The Board agreed with the view put forward by the Government of Travancore-Cochin that all institutions including those aided by local body or charity or voluntary subscription, all private hospitals, dispensaries, nursing homes etc. run by registered medical practitioners or dispensaries run by factories, States etc. should be removed from the scope of the exemption clause provided at item 5 of Schedule K to the Drugs Rules. It was however considered that those medical practitioners who dispense drugs only for the use of their patients and stock only small quantities and who do not keep open shops or sell across the counter or who are not engaged in importation, manufacture or distribution of drugs on a commercial basis should continue to enjoy the benefit of the exemption.

Item IV of the Agenda—To Examine what excess unitage should be added to allow for deterioration of Potency of Sera and Anti-Toxins on Storage

The Board was of the opinion that the recommendation of the storage sub-committee that excess unitage should be added to sera and anti-toxins to off-set loss of potency on account of storage conditions, was only of a advisory nature meant for the guidance of manufacturers. Lyophilised sera and vaccines and those prepared according to the "enzymetreated" methods need not contain any excess unitage. The Board was therefore of the view that the recommendation of the storage sub-committee in regard to addition of excess unitage should not be made mandatory.

Item V of the Agenda—Consideration of the question whether household remedies like Soda-Bicarb, Soda-Mint, Anacin etc. should be allowed to be sold by unlicensed dealers

Letter dated the 6th October, 1954 from Dr. Ray was discussed. The Board was of opinion that the suggestion made in the letter was impracticable.

Item VI of the Agenda—To consider the question whether control over the manufacture of Kahn's Antigens and other similar products should be exercised or not

Colonel Ahuja explained that Kahn's antigen, being a diagnostic reagent, would not be controlled as a drug in terms of its existing definition in the Drugs Act. He added that there were a number of diagnostic agents and that though it would be advisable to control them under some legislation,

it would entail fundamental and far-reaching changes in the Drugs Act if it were intended to control them under the latter legislation. The Board agreed with him and was of the view that it would not be possible to control the manufacture of Kahn's antigen under the Drugs Act.

Incidentally, the Board felt that the term "antigens" appearing in Schedule "C" to the Drugs Rules should be changed to "Immunizing antigens" if it was necessary to explain the nature of antigens covered by the Drugs Act.

Item VII of the Agenda—To consider Letter No. D.F./SIV-15/11512, dated 13-8-54 from the Director of Medical and Health Services, U.P., Lucknow

The Board considered letter from the Director of Medical and Health Services, U.P. and felt that apart from making it obligatory, for the date of manufacture to be shown on the labels of schedule C(1) drugs, it would not be practicable to lay down any life period for such drugs as well as other volatile drugs owing to lack of adequate data on the subject.

Item VIII of the Agenda—To consider the Question whether from the entry "Paraminobenzensulphonamide; its Salts; Derivatives....." In Schedule H to the Drugs Rules 1945, the excluding entry "Preparations and Dressings containing these for Extenral use" should be so amplified as to cover eye drops, ear drops, nasal drops and pessaries within it

The Board was of opinion that eye drops, ear drops, nasal drops and pessaries containing sulpha-drugs should be considered as preparations for external use and exempted from the provisions of rules 65(9) and 96(1) (c).

Item IX of the Agenda—Any other matter allowed by the Chairman

(1) The Board considered letter No. F. 11-22/54-DS, dated the 16th October, 1954 from the Government of India, Ministry of Health (appendix) and agreed to the addition of the proviso to Rule 23 as suggested therein. It was also of the view that the existing form 12 could not be adapted to cover imports of drugs for personal use and therefore recommended the introduction of a new form 12-A for the purpose.

(2) Dr. J. C. Gupta desired that the scope of rule 124(3) should be so amplified as to cover preparations included in the earlier editions of all the recognised pharmacopoeias other than the B. P. It was explained that the question was already under consideration of the Government of India.

(3) Dr. Nanji stated that a machinery should be devised to keep the list of poisons in the Drugs Rules up-to-date. It was decided that, if the Poisons sub-committee could not meet more often, steps should be taken to carry out the work of the sub-committee by correspondence in order to keep the poisons list up-to-date.

(4) Dr. Nanji also suggested that the recommendations of the Storage sub-committee should be examined and such of its recommendations as are considered necessary should be made mandatory by making suitable provisions in the Drugs Rules. The Board agreed that this question should be examined further.

(5) Dr. K. K. Sen Gupta desired that the excise duty on drugs should be assessed on a uniform basis throughout the country. It was explained that the question did not fall within the functions of the Drugs Technical Advisory Board. It was, however, pointed out for the information of the Board that the Central Government had already brought out a Bill for the purpose.

The meeting terminated with a vote of thanks to the Chair.

APPENDIX

Copy of letter No. F. 11-22/54-DS, dated the 16th October, 1954 from Shri Krishna Bihari, M.A., Under Secretary to Government of India, Ministry of Health New Delhi to the Secretary, Drugs Technical Advisory Board, (Shri P. M. Nabar) C/o The Directorate General of Health Services, New Delhi.

SUBJECT :—*Import of small quantities of "new drugs" for treatment of particular patients—Provision for import.*

I am directed to say that it has been suggested that the following additional provisos may be made in the existing rule 23 of the Drugs Rules, 1945:

"Provided that such drugs imported for personal use but not forming part of *bona fide* personal baggage shall be permitted to be imported without a licence subject to the following conditions :—

(i) the licensing authority is satisfied that the drug is for *bona fide* personal use; and

(ii) the quantity involved is reasonable for the purpose in the opinion of the Licensing Authority and is covered by a prescription from a registered medical practitioner."

I am to request that the Drugs Technical Advisory Board may be consulted and their opinion communicated to the Government of India at a very early date.

2. I am also to suggest that the Board may consider whether the existing form 12 to the Drugs Rules will be sufficient for the purposes of import of new drugs of the nature mentioned above, or whether a new form should be prescribed for this purpose. In case the Board considers that a new form would be necessary, the draft of a new form may also kindly be sent to the Government of India.

GIPN—S2 I M. of Health/58—(15th Metting)—26-12-59—400.