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GOVERNMENT OF INDIA

MINISTRY OF HEALTH

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

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AGENDA FOR THE TWELFTH MEETING OF THE DRUGS TECHNICAL ADVISORY BOARD

I. Confirmation of the minutes of the eleventh meeting.

II. Consideration of the following questions arising out of the proceedings at the last meeting :—

(a) *Para* 5 *of the minutes.*—The question of fixing a 'life period' for cholera vaccine after taking into account the following : —

(i) Letter No. 20/10/50-R, dated 18th December, 1950 (Enclosure A).

(ii) A note submitted by Dr. Gallut to W. H. O. on the standardisation of cholera vaccines (Enclosure B).

(b) *Para* 20 *of the minutes.*—The minutes of the first three meetings of the Poisons Sub-Committee for consideration and approval. (Enclosure X and Y to the Agenda of the tenth meeting and enclosure C to this Agenda).

(c) *Para* 21 *of the minutes.*—Question whether injectible preparations of Ayurvedic and Unani Systems of medicine should not be controlled under the provisions of the Drugs Act, *Vide* letter No. 12/12/49-R, dated 27th January 1951 from the Indian Council of Medical Research (Enclosure D).

(d) *Para* 22 *of the minutes.*—Reconsideration of Rules 65(5) of the Drugs Rules in the light of :

(i) the comments received on the minutes from some members (Enclosure E).

(ii) the Government of India Letter No. F. 1-20/49, dated the 21st July 1950 forwarding views of the PAMDAL (Enclosure F).

(e) *Para* 25 *of the minutes.*—Reconsideration of the question whether the addition of harmless colouring matter in B. P. tinctures and spirituous preparations should be allowed or not (Enclosures G and H).

(f) *Para* 26 *of the minutes.*—Consideration of the letter dated the 10th February 1950 from Dr. Jivraj N. Mehta regarding relaxing the provisions for (qualified person in the light of the remarks from the Pharmacy Council of India. (Enclosure I).

(g) *Para* 34 *of the minutes.*—Endorsement No. F.6-/50-DS, dated the 25th April 1950 regarding introduction of provisions in schedule F in respect of B. C. G. vaccine (Appendix V to the minutes of the eleventh meeting).

(h) *Para* 36 *of the minutes.*—Consideration of letter No. 29/50, dated the 27th February 1950 from the All India Chemists and Drugists Federation, New Delhi, (Appendix VII to the minutes of the eleventh meeting suggesting that the sole agency clause for the import of Schedule C drugs should be done away with).

III. Consideration of the following communications received from the Government of India, Ministry of Health :—

(1) Letter No. F. 1-9/48-D, dated the 26th June 1950 Drugs Rules, 1945—Amendment of Sub-rule (2) of Rule 108—Penicillin in single dose containers (Enclosure J).

(2) Letter No. F. 1-7/50-DS, dated the 18th August 1950—Amendment to the Drugs Rules, 1945—Consideration of Dental Surgeons to be treated as 'registered medical practitioners' (Enclosure K).

(3) Letter No. F. 1-1/47-D, dated the 17th August 1950—Amendment to the Drugs Rules 1945—Patent and Proprietary Medicines. (Enclosure L).

(4) Letter No. 2214-DS/50, dated the 7th November 1950—Fixation of "Poison" labels on certain items (Enclosure M).

(5) Letter No. F. 1-13/50-DS, dated the 13th December 1950—Labelling non-biological drugs not included in Schedule E (Enclosure N).

(6) Letter No. F.1-1/51-DS, dated the 17th January 1951—Amendment of the Drugs Rules with a view to permitting the import of Schedule C and C(I) drugs for personal use and for use in Missionary Charitable and other institutions without import licences. (Enclosure O).

(7) Letter No. F. 1-9/51-DS, dated the 8th May 1951—Question whether Sulpha drugs can be sold by unqualified persons. (Enclosure P).

(8) Letter No. F. 1-19/50-DS, dated the 12th May 1951—Exemption regarding Epsom Salt prepared from sea water (Enclosure Q).

(9) Letter No. F.1-12/48-D, dated the 7th June 1951—Rules 65(1) and 65(3). Amendment of (Enclosure R).

(10) Letter No. F. 1-13/51-DS, dated the 14th June 1951—Rule 32 of the Drugs Rules. Amendment of (Enclosure S).

(11) Letter No. F. 1-14/50-DS, dated the 15th June 1951—Amendment to Schedule F of the Drugs Rules (Enclosure T).

IV. Consideration of the following :—

(1) Amendment relating to the provisions for antivenum serum in the Drugs Rules Section L Para 5(1) (a) as proposed by the Director, Central Research Institute, Kasauli (Enclosure U).

(2) Question whether form 8 in the Drugs Rules, 1945, should be amended so as to indicate that the applicant has got a licence to sell drugs (Enclosure V).

(3) Letter No. 04-M/D/633, dated the 4th November 1950 from Mr. S. P. Sen, a member of the Drugs Technical Advisory Board. Standard for final product (Enclosure W).

(4) D. O. Letter No. SV/3812/A, dated the 1st March 1951, from the Director, Central Research Institute, Kasauli—Standard for Tetanus Anti-toxin (Enclosure X).

(5) D. O. Letter No. SV/12501/A, dated the 28th June 1951 from the Director, Central Research Institute, Kasauli—Suggestion to exclude certain items from schedule F of the Drugs Rules. (Enclosure Y).

V. Any other business allowed by the Chairman.

ENCLOSURE A.

COPY OF LETTER NO. 20/10/50-R, DATED THE 18TH DECEMBER, 1950, FROM THE SECRETARY, GOVERNING BODY & SCIENTIFIC ADVISORY BOARD, INDIAN COUNCIL OF MEDICAL RESEARCH, NEW DELHI, TO THE SECRETARY, DRUGS TECHNICAL ADVISORY BOARD, DIRECTORATE GENERAL OF HEALTH SERVICES, NEW DELHI.

SUBJECT :—*Cholera vaccine—life period of.*

With reference to your letter No. 9-14/50-DAB, dated the 27th September, 1950, I am directed to say that the question regarding fixation of life period of Cholera Vaccine was placed for consideration before the meeting of the Cholera Advisory Committee of the Indian Council of Medical Research held in Agra on the 28th November, 1950. The relevant extract from the report of the meeting of the Cholera Advisory Committee is enclosed for your information.

EXTRACT FROM THE REPORT OF THE MEETING OF THE CHOLERA ADVISORY COMMITTEE OF THE I.C.M.R. HELD IN AGRA ON THE 28TH NOVEMBER, 1950.

To consider a letter from Mr. P. M. Nabar, Secretary, Drugs Technical Advisory Board, Directorate General of Health Services, New Delhi, regarding fixation of life period of Cholera Vaccine :

The Committee is of the view that the question of the life period of Cholera Vaccine is intimately tied up with that of an official standard of potency of the vaccine which is now under the consideration of the Biological Standardisation of the W.H.O. The Committee do not consider it desirable to suggest an interim standard. They are therefore of the opinion that there are no grounds to recommend any variation from current practice in India which recognises a life period of 18 months for Cholera Vaccine.

ENCLOSURE B.

UNITED NATIONS
WORLD HEALTH
ORGANIZATION

NATIONS UNIES
ORGANISATION MONDIALE
DE LA SANTE

Expert Committee on Biological Standardization

WHO/BS/69

4 *May* 1949.
Original : FRENCH

On The Standardization of Cholera Vaccines

Note submitted by Dr. J. Gallut, Chief of Laboratory, Institute Pasteur, Paris

I. LYOPHILIZED STRAINS :

The only advantage justifying the application of this method to cholera vibrios would appear to be its stabilizing effect on the antigentic constitution

of the strains. We do not consider that the maintenance by the usual methods (inoculation on bouillon-agar in sealed tubes with bionnial subculturing) is necessarily inferior. Using this latter technique we have, in fact, amongst our collection certain examples of strains which can be relied upon to maintain their antigenic structure for 10 years or more.

II. Freezed Vaccines:

In our opinion this procedure entails practical complications in vaccination practice, which do not justify an indiscrimintae use of this vaccine in large populations.

Nevertheless, the freeze-drying of original suspensions to serve as a stock vaccine might be considered in the case of a polyvalent anticholera vaccine.

III. O-antigen :

Since 1935 we have known that the cholera vibrio contains two sorts of antigens: the thermolabile "H" and the thermostable "O".

These antigens have been considered since then to consist of the non-specific "H" and the specific "O". The recent work of Burrows (1) and of Gallut (2) have shown that the complexity of the O-antigen, which may be separated into 13 different antigenic factors of various importance, and were given the letters A, B, C, D..... M, and classified as follows:

1 fundamental specific factor A.

12 accessory non-specific factors : 2 major B and C 10 minor D, E, F....M.

With the exception of the A factor, all these factors can be present in any vibrio.

A special importance should be attached to factors B and C when they occur in association with the factor A, for these factors B and C are characteristic of the three varieties of known cholera vibrios whose "O" structure is the following :

OGAWA=AB—DEF.....M.

INABA=AC—DEF.....M.

HIKOJIMA=ABC—DEF.....M.

The existence of a fourth new type of structure consisting exclusively of A has been described by Burrows and confirmed by Gallut.

IV. Agglutinating Sera :

From a complete analysis of antigen C it appears that for the future diagnosis of cholera and specific anti-A serum should be used instead of the Ogawa and Inaba sera in common use which were prepared from strains, the structure of which is not completely known. In this manner, it is possible to avoid all agglutination due to non-specific factors and it no longer becomes necessary to fix an arbitrary titro of minimum agglutination higher than 1% is valid since the normal serum of rabbits never agglutinates cholera vibrios at more than 1 in 50.

Further, accurate type diagnosis requires the use of specific B and C sera, which alone are capable of preventing coagglutination which may occur with any Ogawa and Inaba sera, even if saturated. These coagglutinations due to the frequent presence of D and E factors might lead to a false type diagnosis.

V. Preparation of Vaccines:

The value of an anti-cholera vaccine is determined by two elements;

One qualitative antigenic specificity of the vibrios used.

The other quantitative: O-antigen content of the dose administered.

We will consider both of these points in succession.

1. Since we know the O-antigen to be complex it is no longer possible to define the cholera vibrio simply in terms of Inaba, Ogaw, or Hikojima, and hence it is no longer correct to speak of "a monovalent vaccine destined to fight an epidemic arising from a single serological type".

In fact to consider the case of the last epidemic, the antigenic investigation of 34 vibrios isolated in Egypt in 1947, all belonging to the Inaba type and containing all the AC factors, showed that they fell into 12 different antigenic formulae, on account of their secondary factors.

It is clear, therefore that the use of a monovalent vaccine prepared with any type of Inaba strain, the complete structure of which is unknown, does not ensure the production of the maximum number of necessary antibodies.

The combined vaccine as prepared in the USA, composed of an equal mixture of one Inaba strain and one Ogawa, shows the same disadvantages, all the more so, owing to the presence of 50% of the B factor not generally found in epidemics.

Due to the lack of information as to the antigenic structure of vibrios, it was found expedient often to make the vaccine from as many strains as possible, which is the practice of the Department of Vaccine Preparation of the Institute Pasteur, when in 1947 the anticholera vaccine was composed of 6 different strains.

2 strains from the National Institute of Health (USA):

No. 35a3 (ACDE).

No. 41 (ABE).

4 strains from Indochina:

Hanoi III (ABCFIKL).

Hanoi VII (ABCFIKL).

Hanoi XVIII (AC).

Saigon 1046 (ABCFIKLM).

As indicated in the following table, the antigenic composition of this vaccine, although preferable to the US type of vaccine, shows by comparison with the structure of a certain number of cholera vibrios from Egypt, 1947, the imperfection of our present methods.

TABLE

Distribution of the percentage of O-antigen factors of the 1947 Egyptian cholera vibrios and anti-cholera vaccine

O Factors	Vibrios from Egypt	Inst. Pasteur Vaccine	US Vaccine
A	100	100	100
B	0	80	50
C	97	80	50
D	55	30	50
E	32	30	100
F	20	50	0
L	40	50	0
(Other factors total)	30	66	0

In order to obtain an optimum specificity of vaccine we consider that only vibrios of completely known antigenic structure should be used. These vaccines should be employed in the following ways;

(a) A polyvalent vaccine for use mostly in epidemic cases and further appropriate for use in any circumstances; it should contain 13 antigenic factors in the following proportions (%) : A=100; and the other 12 factors in proportions equal to or approaching 50%.

(b) A vaccine, destined to fight a given epidemic, should have antigenic composition identical to that of a sufficient number of the vibrios responsible as shown by analysis.

2. The O-antigen content of the injected dose depends on two elements; one, the O-antigen content of the strains used, and, two, the number of organisms per cc.

It is easy to estimate the total O-antigen of a given strain by using one of the existing techniques (such as Boivin's test, with trichloracetic acid). Strains which have adequate yield, *i.e.,* at least equal to 5 per cent of the dry weight, will have to be used [Gallut (3)].

On the other hand, it is fully realized that is difficult to make an exact determination of the number of organisms by direct numeration or by opacity tests on account of the variations in size of the vibrios and on account of antolysis. It would be more precise to express the vaccinating dose by weight of bacilli or better still in terms of O-antigen weight.

It is noteworthy in this respect that the methods of culture of the cholera vibrios resorted to has an effect upon the yield of O-antigens: attempts to culture cholera vibrios by an intense aerobic method passing through air and OO2 in a liquid glucose bicarbonate medium containing very little nitrogen [Gallut (4)] resulted in an-O-antigen content three times as high as that obtained on the usual agar medium.

The estimation of O-antigen by weight is in all respects a more rational method of estimation than based on the number or weight of the organisms present.

The weight of total O-antigens contained in a dose of vaccine sufficient for an adult (administered preferably in two injections) may be estimated as being about 0.1 mg.

Summary

Anti-cholera vaccines should be prepared so as to have a known anigenic structure and a definite O-antigen content.

References :

(1) Burrows, W. Mather, A. N., McGann, V. G., and Wagner, S. M. J. inf. Dis. 1946, **79,** 168-194.

(2) Gallut, J., Annales 1. Pasteur, 1949, **76** 122-135.

(3) Gallut, J., *Ibid.,* 1943, **69** 123-126.

(4) Gallut, J., *ibid.,* 1947, **73**, 650-660.

ENCLOSURE C.

AGENDA FOR THE MEETING OF THE SUB-COMMITTEE OF THE DRUGS TECHNICAL ADVISORY BOARD APPOINTED TO EXAMINE SCHEDULE E TO THE DRUGS RULES (MEETING TO BE HELD ON 7-5-1950)

(1) Examination of Schedule E to the Drugs Rules *vis-a-vis* the Poisons Rules framed by State Governments under the Poisons Act 1919 with a view to finding out the extent of their overlapping.

(2) Reconsideration of Bombay Government's letter (Enclosure F to the Agenda of the sub-committee meeting held on 15th November 1949) with reference to para 12 of the minutes of the sub-committee meeting held on 15th November 1949.

(3) Any other business allowed by the Chairman.

MINUTES OF THE THIRD MEETING OF THE POISON'S SUB-COMMITTEE OF THE DRUGS TECHNICAL ADVISORY BOARD HELD IN THE OFFICE OF THE DIRECTOR GENERAL OF HEALTH SERVICES, NEW DELHI, ON 7TH MAY, 1950.

The following were present:—

Dr. A. K. SEN (*Chairman*).

Dr. B. N. GHOSH.

Dr. B. MUKERJEE.

Shri S. P. SEN.

Shri P. M. NABAR (*Secretary*).

Dr. U. P. Basu and Mr. P. S. Ramachandran were present by special invitation.

Dr. A. K. Sen was elected to the Chair.

Item No. 1 of the agenda.—Before this question was taken up for discusion, the chairman enquired whether the provisions of the Poisons Rules in the States were in addition to those of the Drugs Rules or in derogation of the latter. The Secretary, Drugs Technical Advisory Board was asked to make a reference to the Government of India and obtain their legal opinion on the point. It was further decided that the Secretary should examine the case in the light of the reply received from the Government.

The following resolution was also passed by the sub-committee:—

"The Poisons Sub-committee of the Drugs Technical Advisory Board recommends that in order to ensure uniformity in the administration of the Poisons Act throughout India, it is necessary that steps be taken as follows:

(1) a uniform and comprehensive Poisons List be adopted by the Central and the State Governments; this list should be kept up-to-date from time to time on the advice of the Drugs Technical Advisory Board;

(2) a uniform set of Rules under the Poisons Act be adopted by the Central Government and the State Governments:

(3) the list of Poisons as well as the Poisons Rules should be printed and made available to the public the medical and the pharmaceutical profession throughout India;

(4) all schedules, forms and Rules should be uniformally numbered and denoted by the Central and the State Government."

Item No. 2 of the agenda.—The only point which required to be considered in the Bombay Government's letter was the suggestion to do away with the proviso to Rule 65(2). The Sub-committee noted the anomalous position in regard to the supply of Schedule E drugs created by the proviso to Rule 65(2) and decided to recommend the deletion of that proviso.

Any other business.—The Sub-committee agreed that "Barberine and its preparations excepting substances containing less than 0·02% of Barberine" should be included in Schedule E.

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

(Sd.) ANIL KUMAR SEN.
(Sd.) S. P. SEN.

(Sd.) B. N. GHOSH.
(Sd.) B. MUKERJI.
(Sd.) P. M. NABAR.

ENCLOSURE D.

COPY OF LETTER NO. 12/12/49-R., DATED THE 27TH JANUARY, 1951, FROM THE SECRETARY, INDIAN COUNCIL OF MEDICAL RESEARCH, P.O. BOX 494, NEW DELHI, TO THE SECRETARY, DRUGS TECHNICAL ADVISORY BOARD, DTE. GENERAL OF H.S., NEW DELHI.

SUBJECT:—*Injectible preparations of Ayurvedic and Unani Medicines—Question of control under the Drugs Act and Rules.*

With reference to your letter No. 8/3/50-DAB, dated the 15th November, 1950 on the above subject, I am directed to say that the Therapeutic Trials Sub-Committee of the Indian Council of Medical Research at its meeting held in November, 1949, had considered a request from Shri Shankerbhai G. Patel of Padra for conduct of clinical trials with an Ayurvedic (injectible) medicine 'Atomized Mica'. The literature on 'Atomized Mica' received from Shri Patel is enclosed for information of the Board.

I am to request that this office may kindly be informed, in due course, of the action taken by the Drugs Technical Advisory Board on the recommendation of the Therapeutic Trials Committee that injectible medicines prepared according to Ayurvedic and Unani system should come under the control of Drugs Act.

The available Scientific information regarding the agent

"Atomized Mica"

1 Composition

A single substance "*Mica* (*Abhrak*)"

1. *Method of preparation.*—One pound of crude black Mica (Abhrak) is purified by heating it on the smokeless fire of the cow-dung and is dipped into the quoth (decoction) of the jujub tree and it is rubbed therein till it is turned into power. Then the mixture is passed through the woollen-blanket, and it is allowed to settle; the water is poured off and the powder is dried up.

The powder is then mixed up with the juice of an Indian herb Rudrawanti (Cresa Cratica) once and is burnt into the Gujuput [an Ayurvedic process of preparing Bhasma (Oxides) *i.e.* furnace of 2′ x 2′ x 2′] in the dung fire. Every two tolas of the Bhasma (oxides) so prepared is ground in the marble mortar and marble pastle for six hours.

Then the same powder is mixed with the juice of the following Indian herbs, *Mandar,* (calotropis prosira) *Kakjanga* (Lia Hirta), *Apamerga* (rough chaph tree), Vasaka (*Adhotoda*) and *Gangavati* (No English name for this) seven times each and is burnt everytime in the Gajput in the consecutive order. Every time every two tolas of it is ground in the marble morter and marble pastle for six hours after every Gajput.

Two tolas of Bhasma thus prepared is boiled in one pound of distilled water to a boiling point and is filtered, and 1 c. c. and 2 c. c. injection ampoules are filled in scientifically *i.e.,* the ampoules are first cleansed and dried up, then filled with the solution, sealed up and sterilized under 20 lbs. of steam pressure for 15 mts. in an autoclave.

2. *Properties.*—Abhrak Bhasma prepared as mentioned above is dissolved in the distilled water; no any other outside ingredient is added therein. All the chemical analysers available in India have expressed their inability to chemically analyse this drug simply because, it is prepared in accordance with the Ayurvedic system of medicine. The copies of their replies are annexed herewith. We have learnt from a private chemical analyser that this "atomized mica" drug contains calcium and sodium chloride. But we think that this is not a complete and proper analysis. "Atomized mica" is easily soluble in the blood system and cannot be detected afterwards.

3. *Pharmacology.*—I. "Atomized mica" destroys tuber bacillie, heals up the ulcers and cavities, roots out cough and fever, and gives new vigour and vitality. Mica is a metal which is considered insoluble; but Abharak Bhasma prepared as above becomes soluble up to 6% Mica (Abhrak) Bhasma is the most specific Ayurvedic medicine for tuberculosis of all kinds, but its bhasma being administered by mouth, to a patient, cures tuberculosis very slowly, while "Atomized Mica" becomes soluble and its sterilized solution administered through the intramuscular or intravenus route is more effective for T. B. and gives a very good result promptly (*i.e.* it checks the fever of the T. B. patient in the first or second stage within 36 hrs. from the first injection).

II. It is painless and harmless and gives no reaction or untoward effects.

III. It is expected to clear out of the body through urination and perspiration.

4. *Other relevant laboratory data.*—"Atomized Mica" being full of best calcium available in its natural form, generally acts all persons alike without exemption.

5. *Results of preliminary clinical studies.*—No complete systematic clinical trial has been taken by any expert investigator though duly requested for the purpose, but some private as well as the Government medical practitioners have tried this medicine and it is found very effective in T. B.; Acute and chronic bronchitis and Asthma; and painless and harmless. The copies of the concerned testimonials are attached herewith.

6. *Conditions for which agent is believed to be of value.*—

1. T. B. of all sorts.
2. Lungs debility.
3. Slow and Remittent fevers.
4. Heart diseases.
5. Acute and chronic bronchitis.
6. Whooping cough.
7. Asthma.
8. General debility after any serious illness.

7. *Proposed dosage and method of administration.*—For adults 2 c. c. and children under 12 years 1 c. c. or less weekly one or two injections according to the severity of the infection.

It is understood that this information will be transmitted to the committee for consideration and if a decision is reached to sponsor an investigation, the information will be transmitted to the respective investigators.

(*Ayurvedic Preparations.*) (*Indian Union Patent No.* 36539 9-1-1947.)

Atomized Mica

A specific Antituberculosis Abhrak Injection.

Description.—"ATOMIZED MICA" Injection is a special preparation of the Abhrak Bhasma specially prepared by the Ayurvedic system in the juice of Indian herbs and plants mostly prescribed for T. B. and Lungs diseases of all sorts and stages. It has no ingredient other than Abhrak Bhasma. Abhrak is itself the best calcium available in its natural form and is widely used from times immemorial in the Ayurvedic system of medicine for T. B. and Lungs and Heart diseases.

Action.—Destroys Tubercle Bacillie, heals up the ulcers and cavities, roots out cough and fever and gives new vigour and vitality.

Indications.—Tuberculosis of all sorts and stages; slow and Intermittent fevers; Bronchitis of all kinds; Whooping Cough; Asthma; General Debility after any serious illness; Uterine diseases; and Lungs and Heart diseases.

Administration.—Can be given intramuscularly as well as Intravenously without any pain or reaction.

Special Features.—Atomized Mica checks the fever of a T.B. patient on the next day of the first injection and thereby gives a new life in a very short period at a little cost.

Dosages.—For adults 2 c.c. and for children under 12 years 1 c.c. or less weekly one or two injections according to the severity of the infection.

Precautions.—The T.B. patient should take food rich in Ghee, Milk, Wheat etc. and should avoid bath, purgatives rice, sour foods and observe celibacy and must take complete rest.

Packing.—Boxes of

6 × 2 c. c. ampoules, Price Rs. 10 per box.

6 × 1 c. c. ampoule, Price Rs. 7½ per box.

(Each c. c. contains 3 mgm. Abhrak Bhasma in distilled water.)

SHREE SHANKER AUSHADHASHALA.
PADRA (G. B. S. RLYS.)
via BARODA (INDIA).

Some Opinions

This is to certify that I have tried 'SHANKERABHRAK' injections on the following cases:—

1. T. B. Lungs 3 years duration.
2. Chronic Bronchitis 7 years duration.
3. Asthma 4 years duration.

All these cases were being treated uptil now on usual allopathic line or treatment with only temporary relief but after starting the 'Shankerabharak' Injections all the three patients are improving nicely and satisfactorily.

PATAN,
24-3-47.

(Sd.) V. S. SHAH,
L.C.P.S. (*Bombay*).

I am very glad to use 'Abhrak' Injections for cases of Chronic Bronchitis. It showed me very good results. Really it is a boon to the chronic sufferers.

PRATAP GUARD,
BARODA ;
Date : 27-1-47.

(Sd.) P. C. SHAH, S.A.S. 2 LT. B.M.S.
Lall Baug Lines Military Dispensary, Baroda.

I am very glad to use Shankerabhrak.

I have found it most effective in a case of Chronic Bronchitis asthma and in a case of pulmonary tuberculosis of first stage.

STATION ROAD,
ANAND :
17-4-45.

(Sd.) B. N. PATEL,
L.C.P. & S. (Bombay).

This is to certify that I have tried 'Shankerabhrak' injection, on the following cases :—

1. Chronic Bronchitis 6 months duration.

2. T. B. Lungs 2 years.

All these patients are improving nicely and satisfactorily.

BARDOLI,
17-9-47.

(Sd.) S. C. SHAH,
M.B.B.S. (Bombay).

ENCLOSURE E.

EXTRACT FROM LETTER DATED THE 23RD JUNE, 1950 FROM DRS. A. K. SEN AND U. P. BASU AND SHRI S. P. SEN.

"Comments on para 22 of the minutes of the eleventh meeting of the Drugs Technical Advisory Board.

The amendment was actually modified after elaborate discussion and the modified amendment was passed and not the amendment as it is. The modification was by the insertion of the words "excluding manufacturers" between "Schedule C" and "shall be recorded etc." and that the modified amendment read as follows :

All purchases and sales by way of wholesale dealing of drugs specified in Shedule C, "excluding manufacturers" shall be recorded in a register, etc.

It was also decided that register should be properly defined."

ENCLOSURE F.

COPY OF A LETTER NO. F. 1-20/49-DS, DATED THE 21ST JULY, 1950 FROM THE GOVERNMENT OF INDIA, MINISTRY OF HEALTH, NEW DELHI TO THE SECRETARY, DRUGS TECHNICAL ADVISORY BOARD, NEW DELHI.

SUBJECT :—*Rule* 65(5) *of the Drugs Rules,* 1945—*Amendment of—regarding maintenance of records or purchases and sales by way of wholesale dealing of schedule C drugs.*

With reference to the correspondence resting with this Ministry's letter of even number dated the 24th March, 1950, on the subject mentioned above. I am directed to forward herewith a copy of letter No. 382 dated

the 27th May, 1950, from the Hony. Secretary, Pharmaceutical & Allied Manufacturers' & Distributors' Association Ltd., Bombay and to request that the same may be placed before the Board at its next meeting. The views of the Board in the matter may be communicated to this Ministry as soon as possible after its next meeting.

COPY OF LETTER NO. 382, DATED THE 27TH MAY, 1950, FROM THE HONY. SECRETARY, PHARMACEUTICAL & ALLIED MANUFACTURERS' AND DISTRIBUTORS' ASSOCIATION LTD., BOMBAY, ADDRESSED TO THE MINISTRY OF HEALTH, NEW DELHI.

SUBJECT :—*Rule* 65(5) *of the Drugs Rules,* 1945.

The substance of your letter No. F. 1-20/49-DS, dated the 17th December 1949 is a proposal of such wide moment that my Committee have deemed it necessary to deliberate upon it for some time.

A new Managing Committee was elected in April of this year and both the out-going committee and the new committee examined the substance of Rule 65 (5), and your proposed amendment to it, most carefully. Both committees were of the opinion that the amendment as proposed, would be unwieldy in the average large scale drug importers' organisation.

We would repeat that we are of the opinion that the amendment, as proposed, is not an easily workable proposition. In a small importing house where only a few dozen items are handled per day, the proposed maintenance of a register is possible; but in a large importing house where many thousands of Schedule 'C' items may be issued daily in small lots, we feel that Government of India will appreciate that a register, or even registers, cannot be easily maintained.

We know of no method of maintaining such registers, other than having the particulars handwritten, in sequence, and not alphabetically. The present systems, adopted by our members, as approved in your letter No. F. 1-12-12/49-D of 26th April 1947, is to *record* all necessary facts upon invoices. It is our view, that inspectors will find the information more readily from clear copies of invoices, rather than from the innumerable handwritten pages contained in a register, or registers.

My committee have had many attempts to formulate an alternative suggestion but it has been obvious from the many varying proposals received individually by the members of both committees, that not one proposal could be adopted by all firms without a serious reorganisation of their business methods.

Our submission, therefore, is that Rule 65(5) should not be amended. It is obvious that the intention of the officers who drafted this rule originally was to make a discrimination between "sales by way of wholesale dealing" and "sales by retail" and we suggest that their intention be not lightly set aside. The word "record" was used in Rule 65 (5) and the word "register" was used in Rule 65 (4), and both words were obviously carefully chosen. Our opinion is, and we hope that the Government will agree with us, that the word "record" was used in Rule 65 (5) to cover any form of record which gives the information required to Government Inspectors. It is our submission, therefore, that the type of record to be maintained by importing and

distributing houses should be that type of record which gives the local drugs controller information which he would require, and we believe that the present system achieves this. We therefore repeat again that we do not agree with the proposed amendment to Rule 65 (5), and suggest that the Rule as it stands is adequate and is more applicable than the proposed amendment.

My committee further submit that Government should take into consideration that the Drugs Rules have been in force for the past 3 years and that during this period there has been no instance where Government have requested an inspection of records of registers in order to recall a batch or a Schedule 'C' article which has been reported to be unserviceable. This Association is willing to extend any assistance to Government in the amplification of the Drugs Act but we must make a proviso that such amplifications will be worthy of the trouble and expense imposed upon our members. Maintenance of registers, apart from being unworkable, would impose a hardship on importing houses, to produce a benefit which is not apparent. Members of this Association, should they suspect a drug or batch to have become unserviceable or toxic would prefer to circularise all their customers immediately without wasting the necessary time, which might be days, required to abstract the information required from a register.

It is realised that there are two aspects to this subject. Your aspect may be purely academic but our aspect is practical. The Government may not have fully considered the trouble and expense this proposed amendment may impose upon the large importers but to impress upon you what it may involve, we would bring to your notice that an interpretation given by the Drugs Controller wherein it was ruled that sales by way of wholesale dealing, mentioned in Rule 65 (5) did not include sales to doctors or hospitals, caused a number of our members to cease sales to the medical profession and to hospitals. Such a step, which was obviously retrograde, was not taken without full consideration and the ultimate decision that registers could not be maintained correctly.

This Association is of the opinion that the practical application or rules under the Drugs Act are more effective than academic directions. As we have stated earlier in this letter the importing pharmaceutical houses who have been doing business in India for a considerable number of years have their own methods of protecting their customers and their reputation from unserviceable batches of Schedule 'C' items. The Rule 65 (5) as it stands at present, permits this practical application, but your proposed amendment, although it may be theoretically ideal will not practically add anything to the protection of the general public.

ENCLOSURE G.

NOTES IN THE MINISTRY OF LAW

Section 18 (a) (i) prohibits the manufacture of a drug which is not of standard quality. The drug, to be of standard quality, must, as required by section 16 (1), comply with the standard set out in the Schedule to the Act. The Schedule to the Act prescribes certain specified standards, which appear to have been based on strength, quality and purity. If the prescribed standards do not permit, either expressly or by necessary implication, the use of

innocuous or inert substances in the manufacture of drugs, the use of such substances will clearly render the drug sub-standard and the manufacture of the drug would be in contravention of section 18(a) (i). It would therefore be necessary to examine the standards prescribed by the Schedule to ascertain whether mixing of colouring agents is permitted by them. If such mixing is not permitted. obviously colouring agents cannot be used in the manufacture of drugs.

COPY OF LETTER NO. 126/132, DATED THE 13TH APRIL, 1951 FROM ASSOCIATION OF BRITISH CHEMICAL MANUFACTURERS, BOMBAY TO THE D.G. OF H. S., NEW DELHI REGARDING CARAMEL COLOURING TINCTURES.

REF. :—*No.* 8-24/50/6/*DAB of April* 12*th.*

In response to the enquiry contained in your above quoted letter, I give below certain information which I have just obtained from our head office in London.

There is no restriction in the U. K. for the use of harmless or inert colouring matter provided that it comes within the Province of the "British Pharmacopoeia" or "British Pharmaceutical Codex" for colouring matters. Manufacturers usually standardize the colour of tinctures etc., to ensure uniformity in colour, if necessary by the use of such colours as caramel etc.

I trust the above information is what you require.

COPY OF LETTER DATED MARCH 16, 1951 FROM THE ASSISTANT TO THE COMMISSIONER FEDERAL SECURITY AGENCY, FOOD AND DRUG ADMINISTRATION WASHINGTON 25 D.C., TO MR. P. M. NABAR, D.G.H.S., NEW DELHI.

We have your recent inquiry concerning the use of added colours in pharmacopoeial preparations.

The Official United States Pharmacopoeia specifically provides for the addition of a colouring material to certain selected articles. For example, the monograph on Absorbent Gauze, page 253 of the U.S.P. XIV, states "Absorbent Gauze may be dyed with a non-toxic dye of low-reflecting capacity." Also, page 2 of U.S.P. XIV contains the statement "In the manufacture of tablets and capsules, it is permissible to use suitable.....colours....."

We think the terms of the Federal Food, Drug, and Cosmetic Act serve to prohibit the use of a colouring material in pharmacopoeial preparations except in those cases where the addition of a colour is expressly provided for by the Pharmacopoeia.

For your information, the Federal Food, Drug, and Cosmetic Act permits the use in non-official drugs of certain coal-tar colours added for purposes of colouring only. We are enclosing a pamphlet containing information concerning these permitted coal-tar colours.

ENCLOSURE H.

COPY OF LETTER DATED THE 3RD JANUARY 1951, FROM DR. J. N. SEN, M.M.F., (MEMBER, STATE MEDICAL FACULTY) WEST BENGAL, STRAND ROAD, CHINSURA, TO THE SECRETARY, DRUGS TECHNICAL ADVISORY BOARD, C/O. DIRECTORATE GENERAL OF HEALTH SERVICES, NEW DELHI.

SUBJECT :—*Addition of Preservatives, Flavouring and/or colouring agents to B.P. and B.P.C. products, when manufactured in a commercial scale.*

As I feel interested in the above matter I beg to place before you the following practical difficulties with a request to kindly let me have your views on the point by an early date.

Instructions in the original B.P. (or B.P.C.) were intended and "drawn up to provide for the preparation (of drugs) by *practising Pharmacist of relatively small quantities*" intended for ready use. As such preservatives, flavouring and/or colouring agents were not incorporated in the formulae. Now, when these products are prepared in a manufacturing scale, necessarily some preservatives are to be added to them to avoid any decomposition or deterioration due to long standing. Similarly, to make the odour more agreeable and to maintain an uniformity in colour, sometimes flavouring and colouring agents are required to be added as well.

Such additions of preservatives, colouring and/or flavouring agents to the B.P. or B.P.C. products have since been practised by the manufacturing chemists to avoid practical difficulties, without of course thereby altering the quality or hampering with the medicinal value of such products in any way.

Following quotation from the British Pharmacopoeia, 1948, General Notices Page-3, lines 11-18, will go to show that additions of substances as suggested above have been allowed.

"The instructions given for the manufacture of Pharmacopoeial extracts, tinctures, ointments and similar preparations are drawn up to provide for the preparation, by the practising pharmacist, of relatively small quantities. If in manufacturing these preparations on a large scale deviations are adopted such deviations must be on points of detail only and the *preparations produced must be identical with preparations* produced by following precisely the instructions of the Pharmacopoeia."

Under the circumstances, I hope, there should be no objection to one's adding the above materials, *viz.*, preservatives, flavouring and/or colouring agents, to the B.P. or B.P.C. products as and when required, *provided that such additions do not in any way alter the percentage of active ingredients or hamper with the medicinal value of the products concerned,* and the results of assay of such products confront with those mentioned in B.P. or B.P.C. as the case may be and mentions of such additions are made in the labels.

Then again in the chapter of Tablets where mention is made regarding colouring or flavouring agents, the B.P. '48 P. 517 recites as follows :—

"*Colouring and flavouring agents.*—The addition of colouring or flavouring agents other than those specified in the monographs, is not official". But as is seen here B. P. does not forbid rigidly such additions. So I presume

that if such additions are made they should be taken as non-official and in that case mention of such additions must be made on the label of the products.

I beg to furnish herewith a list of few of the B.P. or B.P.C. products where such additions as noted against them are felt necessary.

An early reply will be thankfully appreciated.

Deviations in B.P. & B.P.C. Products.

1. Liq. Arsenicalis (B.P.) . . .	Preservative : para-hydroxy Benzoic Acid 0.1% w/v.
2. Liq. Bismuth et. Ammon Citras (B.P.C.)	Preservative : Chloroform 0.14% v/v.
3. Syrup Aurantii (B.P.) . . .	Preservative : Benzoic Acid 0.0628% w/v
4. Syrup Hypophos of Lime (B. P. C.) .	Preservative : Benzoic Acid 0.52% w/v. Alcohol 0.8% v/v. Colouring Agent : Amaranth Red 0.156% w/v. Aromaties 0.08% v/v.
5. Syrup Codein Phos (B.P.C.) 6. Simplex B.P. (Syrup) 7. Syrup Pruni Virgin (B.P.) . .	Preservative : Benzoic Acid 0.1% w/v.
8. Syrup Tolutanus (B.P.) . . .	Preservative : Benzoic Acid 0·1% v/v. Alcohol 2% v/v.

ENCLOSURE I.

COPY OF LETTER NO. 9-14/50-DAB., DATED THE 27TH SEPTEMBER, 1950, FROM THE SECRETARY, DRUGS TECHNICAL ADVISORY BOARD, DIRECTORATE GENERAL OF HEALTH SERVICES, NEW DELHI TO THE SECRETARY, THE PHARMACY COUNCIL OF INDIA, NEW DELHI.

I am to send herewith an extract from a letter sent to this Directorate by Hon'ble Dr. Jivraj N. Mehta, Minister, State of Bombay. This letter was placed before the Drugs Technical Advisory Board at its last meeting for its consideration. The Board decided that before the matter may be considered by it, the relevant extracts from the letter should be forwarded to the Pharmacy Council of India for its opinion.

It is, therefore, requested that the views of the Council may kindly be obtained in the matter and forwarded to me in due course.

EXTRACTS FROM LETTER DATED 19-2-50 FROM DR. JIVRAJ N. MEHTA, MINISTER, STATE OF BOMBAY TO THE DIRECTOR-GENERAL OF HEALTH SERVICES.

I would refer you to Rule 21 and 65(15) under the Drugs Act, 1940. It is laid down therein that for the sale of Drugs the premises should be under the direct and personal supervision of a qualified person. It has also

been defined as to who is to be considered a qualified person for the purpose. Taking the facts as they are it would be seen that the country has very few persons who hold degrees or diplomas in Pharmacy or Pharmaceutical Pharmacy who can be in charge of such premises. As a matter of fact the utilisation of the very few really qualified persons that we have in the country would be a misuse of their knowledge and abilities which for the time being should be utilised in drug manufacturing concerns. We have not even enough persons with four years of practical experience in dispensing that they may meet the approval of the licensing authority to be considered as qualified persons for the purpose. Most of the persons coming in the latter category have poor general education. Most of the drug stores in big cities like Bombay, Madras, Calcutta, Delhi, Lucknow, Patna, Nagpur, Ahmedabad, Poona and even in somewhat smaller cities are private concerns. They have carried on satisfactory business for years. It would be wrong to place these premises "under the personal supervision of a qualified person as defined above" as stated in the rules, if the name plate of Chemist, Pharmacists &c. is to be used. To put such a premium on persons of so little general education and ability, and with a knowledge of mere four years' dispensing would do more harm than good to the national economy.

I would therefore suggest some relaxation, say for a period of seven years by which time a fairly large number of persons could be trained now that Colleges of Pharmacy are being established in different parts of the country. As Provincial Governments and others come to know of this channel for the employment of educated persons with better prospects in life, more such institutions would be developed or better educated persons belonging to better strata in society would come forward to be trained as compounders. In the interest of the trade as well as the general public it may be made permissible to the existing firms to continue to sell in small quantities or split packings made from bulk packings or in original packings and be considered as "qualified" under the rules. They may however be prevented from dispensing prescriptions unless a duly qualified person is employed. If desired, no new premises may be permitted to bear the name-plate of chemists, pharmacists &c. unless they engage a qualified person. Looking to the paucity of such persons, such a restriction even for the next five years would indeed be a hardship to the general public. You and the Technical Advisory Board may give your thoughts to the suggestions herein made.

COPY OF LETTER NO. 16-26/50-PCI(D)., DATED 15-3-51, FROM THE SECRETARY, PHARMACY COUNCIL OF INDIA, TO THE SECRETARY, DRUGS TECHNICAL ADVISORY BOARD, DIRECTORATE GENERAL OF HEALTH SERVICES, NEW DELHI.

I have the honour to refer to your letter No. 9-14/50-DAB., dated the 27th September, 1950, and to say that it was placed before the Pharmacy Council of India at the meeting held on the 12th March, 1951. The council noted that Dr. Jivraj N. Mehta, in his letter dated the 10th February, 1950 had suggested the relaxation of the following provisions in the Drugs Rules to the extent mentioned against each :—

(i) The provision that no dealer in drugs can style his premises as "chemists", "Druggists", "Pharmacists" etc., unless he has employed the services of a qualified person should be relaxed for a period of seven years, and

(ii) The provision that supply in retail of certain categories of drugs which require the services of a qualified person should not be insisted upon.

The Pharmacy Council considered the above suggestions in all their aspects and it was generally felt that their acceptance would go against the spirit of the Pharmacy Act.

ENCLOSURE J

COPY OF LETTER NO. F. 1-9/48-D., DATED 26-6-50, FROM THE GOVT. OF INDIA, MINISTRY OF HEALTH, NEW DELHI TO THE SECRETARY, DRUGS TECHNICAL ADVISORY BOARD, NEW DELHI.

SUBJECT.—*Drugs Rules,* 1945—*Amendment of sub-rule* (2) *of rule* 108.

I am directed to refer to paragraph 25 of the minutes of the eighth meeting of the Drugs Technical Advisory Board and to say that it has been pointed out to the Government of India that Penicillin in liquid form is manufactured and sold both in United Kingdom and United States of America mostly in multiple-dose containers and that the liquid is not required to contain any antiseptic. In view of this I am to request that the matter may kindly be placed before the Board again for reconsideration and its views communicated to this Ministry.

ENCLOSURE K

COPY OF LETTER NO. F. 1-7/50-DS., DATED THE 18TH AUGUST, 1950, FROM THE UNDER SECRETARY TO THE GOVERNMENT OF INDIA, MINISTRY OF HEALTH TO THE SECRETARY, DRUGS TECHNICAL ADVISORY BOARD, NEW DELHI.

SUBJECT :—*Drugs Rules,* 1945—*Amendments to—Dental Surgeons (registered under the Dentists Act,* 1948) *to be treated as 'registered medical practitioners' under the—*

I am directed to refer to this Ministry's endorsement No. F. 1-7/50-DS., dated the 1st May, 1950, on the above subject and to say that 11 Part A State Governments have agreed to the proposal. 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 concerned and the views of the Board communicated to this Ministry in due course.

COPY OF LETTER NO. F. 1-7/50-DS., DATED THE 1ST MAY, 1950, FROM THE UNDER SECRETARY TO THE GOVERNMENT OF INDIA, MINISTRY OF HEALTH NEW DELHI TO ALL PART A STATE GOVERNMENTS.

SUBJECT :—*Drugs Rules,* 1945—*Amendments to—Dental Surgeons (registered under the Dentists Act,* 1948) *to be treated as 'registered medical practitioners' under the—*

The Government of India consider that it is necessary to place Registered Dentists on the same footing as Registered Medical Practitioners in order that they may not have to take out licences for the supply of drugs to their

patients and may not be precluded from prescribing schedule H drugs etc. in the course of their dental practice. It is, therefore, proposed to amend the Drugs Rules, 1945 as in the draft notification attached after consulting 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. 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 Rules can be taken after the views of the Board are obtained.

2. I am also to suggest that if the State Government have no objection, the 'Registered Dentists' may be treated on the same footing as 'Registered Medical Practitioners' for the purpose of Drugs Rules pending the introduction of the proposed amendment to those Rules.

Draft Notification

The following draft of certain further amendments to the Drugs Rules, 1945, which it is proposed to make in exercise of the powers conferred by sections 12 and 38 of the Drugs Act, 1940 (XXIII) of 1940 is published as required by the said sections for the information of all persons likely to be affected thereby and notice is hereby given that the draft will be taken into consideration on or after the . Any objections or suggestions which may be received from any person in respect of the said draft before the date specified will be considered by the Central Government.

Draft Amendments

In rule 2 of the said Rules *after* clause (c) the following clause shall be *inserted* namely :—

(cc) 'Registered medical practitioner' includes a registered dentist.

ENCLOSURE L

COPY OF LETTER NO. F. 1-1/47-D., DATED THE 17TH AUGUST, 1950, FROM THE GOVERNMENT OF INDIA, MINISTRY OF HEALTH, NEW DELHI TO THE SECRETARY, DRUGS TECHNICAL ADVISORY BOARD, NEW DELHI.

SUBJECT :—*Drugs Rules,* 1945—*Amendment to—Patent and Proprietary medicines.*

I am directed to refer to this Ministry's letter No. F. 1-1/47-D., dated the 29th December, 1949, (copy enclosed), and to say that all Part A State Governments (except Madras) have agreed to the Drugs Technical Advisory Board being consulted in the matter. I am to request that the comments received from the Madras Government may be placed for consideration before the Board at their next meeting and their views communicated to this Ministry in due course.

COPY OF A LETTER NO. F. 1-1/47-D., DATED THE 29TH DECEMBER, 1949, FROM THE GOVERNMENT OF INDIA, MINISTRY OF HEALTH, NEW DELHI TO ALL PROVINCIAL GOVERNMENTS (EXCEPT MADRAS).

SUBJECT :—*Drugs Rules,* 1945—*Amendments to—Patent and Proprietary medicines.*

I am directed to refer to the correspondence resting with your reply to this Ministry's letter No. F. 1-15/48-D., dated the 14th/15th September, 1948 and to enclose a copy of letter No. 89532-GI/48-1 PH., dated the 24th January, 1949, with enclosure, from the Government of Madras, in respect of the inclusion of item 4 "Patent or Proprietary medicines in general" in Schedule K of the Drugs Rules. The Government of India will be grateful to have the views of the Provincial Government on the Madras Government's letter at an early date.

COPY OF LETTER NO. 89532-G1/48- P.H. DATED THE 24TH JANUARY, 1949, FROM THE GOVERNMENT OF MADRAS TO THE GOVERNMENT OF INDIA, MINISTRY OF HEALTH.

SUBJECT :—*Drugs Rules,* 1945—*Miscellaneous amendments.*

I am directed to invite a reference to this Government's proceedings No. 3357 P. H. dated 1st October, 1948 on the subject mentioned above (copy of which has been sent to Government of India) and to enclose copy of a letter received from the Surgeon General with this Government regarding the inclusion of item 4, patent or proprietary medicines in general in Schedule K of the Drugs Rules, 1945. This Government agree with the Surgeon General and request that the matter may be placed before the Drugs Technical Advisory Board again and its views communicated to this Government at an early date.

I am also to enquire whether the amendments except the one mentioned above may now be confirmed as no objections or suggestions have been received with regard to them.

COPY OF LETTER FROM SURGEON GENERAL, IN P. NO. 47-D/48, DATED 27TH NOVEMBER 1948.

SUBJECT :—*Drugs—Madras Drugs Rules,* 1945—*Miscellaneous amendments —published.*

The Director, King Institute, Guindy who was consulted in the matter considers that an objection should be entered against the proposed amendment to the Madras Drugs Rules 1945, to include in Schedule K new item 4 regarding patent and proprietary medicines for the following reasons. I agree with them.

1. The nature and quantum of protection to the importer or manufacturer in the matter of disclosure of the composition of the patent or proprietary medicines are contained in Section 10 and Section 18 of the Drugs Act, 1940 read with the explanations under the Sections. If it is not the intention to alter or extend the protection, a change in the Rules framed under the Act is unnecessary.

2. In the case of patent and proprietary medicines, which escape the necessity for analysis and approval by the Central Drugs Laboratory required for registration, by reason of the disclosure of the composition of the drug on the label, a relaxation of the rules would be undesirable in public interest. The disclosure must be full and complete and no reputable manufacturer of drugs would wish to withhold relevant information.

3. From the point of view of analysis, failure to mention all the ingredients and their approximate quantity would render the correct estimation of the patent and poisonous substances contained in the drug difficult by reason of the presence of undisclosed constituents and interferring substances which have to be allowed or eliminated.

4. In the absence of provisions in the Act and the Rules, similar to those contained in Section 505 of the United States Federal Food Drugs and Cosmetics Act, further relaxation of the requirements regarding disclosure of the composition of the medicine will be against public interest.

5. Substances which, by reason of the fact that they are not ordinarily used as medicines, are not included in the Schedule of patent and poisonous substances, may be used as vehicles or diluents for drugs and escape notice by non-disclosure and cause great harm. The tragedy caused in the United States by the sale of Elixir Sulfanilamide is probably now familiar to all.

These remarks embody the views of the Government analyst also.

EXTRACTS FROM LETTER NO. 1-15/48-D., DATED THE 14TH/15TH SEPTEMBER 1948, FROM THE ASSISTANT SECRETARY TO THE GOVERNMENT OF INDIA, MINISTRY OF HEALTH TO ALL PROVINCIAL GOVERNMENTS.

* * * *

Schedule K—

(1) *After* item 3 the following item shall be *inserted*, namely :—

"4. Patent or Proprietary medicines in general.	The provisions of clause (d) of, read with the explanation to, section 10, and the provisions of sub-clause (iii) of clause (a) of, read with explanation to, section 18 of the Act shall not apply so as to require the formula or list or ingredients displayed on the label or container to indicate those in the composition of the medicine which are not patent and not poisonous."

(2) Items 4, 5, 6 and 7 shall be *renumbered* as items 5, 6, 7 and 8 respectively.

ENCLOSURE M

COPY OF LETTER NO. 2214-DS/50, DATED THE 7TH NOVEMBER, 1950, FROM THE GOVERNMENT OF INDIA, MINISTRY OF HEALTH, NEW DELHI TO THE SECRETARY, DRUGS TECHNICAL ADVISORY BOARD, NEW DELHI.

SUBJECT :—*Fixation of "Poison" labels on certain items.*

I am directed to enclose a copy of letter No. 04M/D/258, dated the 26th June, 1950, from M/s. Bengal Chemical and Pharmaceutical Works Ltd., Calcutta, to the Drugs Controller, India and to request that it may

kindly be placed for consideration before the Drugs Technical Advisory Board at their next meeting and the views of the Board communicated to this Ministry.

COPY OF A LETTER NO. 04-M/D/258, DATED THE 26TH JUNE, 1950, FROM THE MANAGER, BENGAL CHEMICAL AND PHARMACEUTICAL WORKS LTD., CALCUTTA, TO THE DRUGS CONTROLLER, INDIA, NEW DELHI.

REF. :—*"Poison" labels on some items.*

We beg to submit herewith a list of items, which according to Schedule "B" of Drugs Rules, 1945 do not require to be labelled as poisons. But these items have been included in the Extended Poison List of P.J. Poison Guide and as such we like to be enlightened at an early date if fixation of poison labels on these items are to be discontinued.

Items :

1. Ether Soap.
2. Ext. Colchici Liq.
3. Ext. Hyoscyamus Liq.
4. Liqr. Hydrarg Perchlor.
5. Lotio Hydrag Nigra.
6. Pill Colocynth et Hyoscyamus.
7. Syr. Codeine Phos.
8. Tinct. Belladonna.
9. Tinct. Colchici.
10. Tinct. Gelsemi.
11. Tinct. Gelsemi.
12. Tinct. Jaborandi.
13. Tinct. Lobelia Ether P.B. '32.
14. Tr. Nux Vomica.
15. Tr. Opii Ammon.
16. Tr. Opii Camphorata.
17. Tr. Stramoni.
18. Vinum Antimonialis.
19. Vinum Colchici.

ENCLOSURE N

No. F. 1-13/50-DS

GOVERNMENT OF INDIA

MINISTRY OF HEALTH

New Delhi, the 13th December, 1950.

FROM

J. N. Saksena, Esquire, B.A.,
Under Secretary to the Government of India,

To

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

SUBJECT :—*Drugs Rules,* 1944—*labelling non-biological drugs not included in Schedule E.*

SIR,

I am directed to forward herewith a copy of letter No. DLA-11-9/50, dated the 22nd August, 1950 addressed by the Director of Health Services, Government of West Bengal to the Drugs Controller, India and to request that the same may be placed before the Drugs Technical Advisory Board at its next meeting. The views of the Board may be communicated to this Ministry in due course.

Yours faithfully,

(Sd.) J. N. SAKSENA,
Under Secretary.

COPY OF LETTER NO. DLA-11-9/50, DATED THE 22ND AUGUST, 1950, FROM THE DIRECTOR OF HEALTH SERVICES, WEST BENGAL, CALCUTTA TO THE DRUGS CONTROLLER, INDIA, NEW DELHI.

I have the honour to inform you that there is no provision in the Drugs Act and the Rules made thereunder on the labelling of those non-biological drugs which are not schedule "E" drugs. Such drugs *viz.* Liq. Iodine, Spt. Bin Iodine, Liniments,ointments etc., which are meant entirely for external application should be labelled "For external use only". Kindly place the proposal before D.T.A.B. and communicate their decision.

ENCLOSURE O

COPY OF LETTER NO. F. 1-1/51-DS., DATED THE 17TH JANUARY, 1951, FROM J. N. SAKSENA, ESQUIRE, B.A., UNDER SECRETARY TO THE GOVT. OF INDIA, MINISTRY OF HEALTH TO THE SECRETARY, DRUGS TECHNICAL ADVISORY BOARD, C/O DIRECTORATE GENERAL OF HEALTH SERVICES, NEW DELHI.

SUBJECT :—*Drugs Rules,* 1945—*Amendment of—with a view to permitting the import of Schedule C and C*(1) *drugs—for personal use and for use in Missionary, Charitable and other institutions—without import licences.*

I am directed to say that the import of Schedule C and C (1) drugs into this country is required to be covered by a valid import licence under the Drugs Act and Rules. The import of small quantities of any drug for the

purpose of examination, test, analysis or for personal use is, however, not subject to the above provisions *vide* rules 24 and 36 of the Drugs Rules, 1945. There have, however, been certain cases of imports of Schedules C and C(1) drugs which were not covered by the exemptions provided in rules 34 and 36 of the Drugs Rules. The drugs were either (i) imported for the personal treatment of *bona fide* patients in this country or (ii) they were imported by charitable and other institutions for the treatment of their patients. In most cases of the first category, covering prescriptions of the medical practitioners were produced and in many cases the drugs were required for the treatment of emergency cases. The use of drugs imported in this way is being allowed by the Drugs Controller (India) under an experimental licence issued on Form 11. Similarly, most of the Missionary institutions in India and Private Charitable Homes have been receiving gifts from abroad for use in the hospitals and institutions which they run. These institutions are unable to secure the necessary Import Licence under the Drugs Act and Rules for the reason that the gifts are collected from various firms and parties in foreign countries and that no manufacturer would appoint a Missionary institution as a 'Sole Agent' or even as an agent for the purposes of the Drugs Act and Rules. Although the above-mentioned imports are not covered by the provisions of rules 34 and 36 of the Drugs Rules, 1945, it is considered that such consignments should not be stopped from being brought into the country so long as the quality of the drugs is up to the required standards. Apart from this, large quantities of drugs are sent to Missionary institutions in India from foreign countries as free gifts and Government would come in for severe criticism if such imports were to be prohibited. In the circumstances stated, it is proposed to make certain amendments in the Drugs Rules, as in the attached draft notification, with a view to permitting the import of Schedule C and C (1) drugs for personal use (not forming part of personal baggage) and for use in Missionary, Charitable and other institutions without the necessity of taking out import licences under the Drugs Act and Rules. I am to request that the proposed amendment to the Drugs Rules, 1945 may be placed for consideration before the Drugs Technical Advisory Board at their next meeting and the views of the Board communicated to this Ministry in due course.

Draft Notification

The following draft of further amendments to the Drugs Rules, 1945, which it is proposed to make in exercise of the powers conferred by section 12 of the Drugs Act, 1940 (XXIII of 1940), is published as required by the said section for the information of all persons likely to be affected thereby and notice is hereby given that the draft will be taken into consideration on or after the.....

2. Any objections or suggestions which may be received from any person in respect of the said draft before the date specified will be considered by the Central Government.

Draft Amendments

In the said Rules, to the existing rule 23 the following provisos shall be added namely :—

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 drugs is for *bona fide* personal use, and

(ii) the quantity involved is reasonable for the purpose in the opinion of the licensing Authority :

Provided further that such drugs shall only be permitted to be imported by charitable, medical or research institutions without a licence as a special case subject to the following conditions :—

(a) the licensing authority is satisfied that they are of standard quality, and that a regular Import Licence cannot be obtained by the importers, and

(b) the drugs are used for the treatment of genuine patients without any distinction, of caste, creed or colour.

ENCLOSURE P

COPY OF A LETTER NO. F. 1-9/51-DS., DATED THE 8TH MAY, 1951, FROM THE GOVERNMENT OF INDIA, MINISTRY OF HEALTH, NEW DELHI TO THE SECRETARY, TO THE GOVERNMENT OF BOMBAY, LOCAL SELF GOVERNMENT AND PUBLIC HEALTH DEPARTMENT, BOMBAY.

SUBJECT :—*Drugs Act and Rules—Question whether sulpha drugs can be sold in original containers by a person who is not a 'Qualified person'.*

With reference to your letter No. 4121/33/9113-H., dated the 17th March, 1951, I am directed to say that the question raised therein is being referred to the Drugs Technical Advisory Board. The recommendations of the Board when received will be communicated to the State Government in due course.

Copy with a copy of the letter under reply forwarded to the Director General of Health Services with reference to his U.O. No. 8-3/51-4-DAB, dated the 23rd April, 1951. It is requested that the question raised by the Government of Bombay may be placed before the Board at its next meeting and the views of the Board in the matter communicated to this Ministry in due course.

COPY OF LETTER NO. 4121/33/9113-H, DATED THE 17TH MARCH, 1951, FROM SHRI V. S. MAHAJANI, DEPUTY SECRETARY TO THE GOVERNMENT OF BOMBAY, LOCAL SELF GOVERNMENT AND PUBLIC HEALTH DEPARTMENT, BOMBAY CASTLE, TO THE SECRETARY TO THE GOVERNMENT OF INDIA, MINISTRY OF HEALTH, NEW DELHI.

SUBJECT :—*The Drugs Act—Renewal of licence under the.*

With regard to the Drugs Act, 1940 and Rules made thereunder a question has arised whether sulpha Drugs can be sold in original containers to laymen by a person who is not a "qualified person" within the meaning of the Act. Sulpha Drugs fall under Schedule E. as well as Schedule H to the Drugs Rules. According to the Drugs Controller for the State of Bombay and also according to the opinion given by the Legal Adviser to the Government of Bombay, sulpha drugs can be sold only on the prescription of a registered medical practitioner and by or under the personal supervision of a qualified person. I am to request you to refer the matter to the Drugs Technical Advisory Board and communicate its views to the Government of Bombay.

ENCLOSURE Q

COPY OF A LETTER NO. F. 1-19/50-DS., DATED THE 12TH MAY, 1951, FROM THE GOVERNMENT OF INDIA, MINISTRY OF HEALTH, NEW DELHI TO THE SECRETARY, DRUGS TECHNICAL ADVISORY BOARD, NEW DELHI.

SUBJECT :—*Drugs Rules* 1945—*Amendment in Schedule K to—Exemption for limit of Chloride Content in Epsom Salt manufactured from sea water.*

I am directed to refer to this Ministry's letter No. F. 1-19/50-DS, dated the 8th January, 1951 and 10th February, 1951, copies enclosed, and to say that all the Part A State Governments have agreed to the proposal contained therein. 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 the State Governments and the views of the Board communicated to this Ministry.

COPY OF LETTER NO. F. 1-19/50-DS., DATED THE 8TH JANUARY, 1951 FROM THE MINISTRY OF HEALTH ADDRESSED TO ALL STATE GOVERNMENTS (PART A).

SUBJECT :—*Exemption for limit of chloride content in Epsom Salt manufactured from sea water—Amendment in Schedule K to the Drugs Rules,* 1945.

I am directed to say that M/s. Tata Chemicals Ltd., Mithapur (Kathiawar) are manufacturing Epsom Salt from marine sources (sea water). It has been found that while this salt contains 0·1% chloride as compared to 0.036% allowed in the B.P. or U.S.P., it is free from lead and arsenic which are allowed up to a certain percentage in the B.P. or U.S.P. It has been represented to the Government of India that an exemption may be granted under the Drugs Act and Rules to cover this variation in chloride content with a view to enabling the manufacturers to market their product. The Government of India are advised that the excess of chloride content which is negligible is not injurious to health and the Epsom Salt can be safely used as drug. Further, it is considered that the manufacture of Epsom Salt from marine sources should be encouraged, particularly with a view to conserving stocks of sulphur which is imported and is required for other important industries. In the circumstances stated the Government of India consider that an exemption should be granted to cover the excess of chloride content in Epsom Salt by the inclusion of an additional clause in Schedule K to the Drugs Rules, 1945, as shown in the attached draft notification, after consulting 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. If the State Government agree, the Central Government will consult the Board on behalf of itself and 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. The favour of an early reply is requested.

Draft Notification

The following draft of certain further amendments to the Drugs Rules, 1945, which it is proposed to make in exercise of the powers conferred by section 33 of the Drugs Act, 1940 (XXIII of 1940), is published as required by the said sections for the information of all persons likely to be affected thereby and notice is hereby given that the draft will be taken into consideration on or after the.....

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

Draft Amendments

In Schedule K to the said Rules, *after* item 8, the following item shall be *added* namely :—

"9. Magnesium Sulphate B.P. or U.S.P.	The provisions of sub-clause (i) of clause (a) of Section 18 of the Act to the following extent :—
	Chlorides present in the salt shall not exceed 0·12% in the case of the product prepared from Sea-water.

COPY OF LETTER NO. F. 1-19/50-DS, DATED THE 10TH FEBRUARY, 1951, FROM THE MINISTRY OF HEALTH ADDRESSED TO ALL PART A STATE GOVERNMENTS.

SUBJECT :—*Exemption for limit of chloride content in Epsom Salt manufactured from sea water—Amendment in Schedule K to the Drugs Rules,* 1945.

I am directed to refer to this Ministry's letter No. F. 1-19/50-DS, dated the 8th January, 1951 and to say that the Government of India are advised that an exemption limit of 0·12% in the chloride content in Epsom Salt should be sought for instead of 0·3%. The exemption limit of 0·12% will approximate to three times the limit of the B.P. and will serve the purpose for which the amendment has been proposed. It is accordingly requested that the figures 0·12% may be substituted for the figure 0·3% in the draft amendment.

ENCLOSURE R

COPY OF LETTER NO. F. 1-12/48-D., DATED THE 7TH JUNE, 1951, FROM THE GOVERNMENT OF INDIA, MINISTRY OF HEALTH, NEW DELHI, TO THE SECRETARY, DRUGS TECHNICAL ADVISORY BOARD, NEW DELHI.

SUBJECT :—*Drugs Rules,* 1945—*rules* 61(1) *and* 65 (3)—*amendment of.*

I am directed to refer to paragraph 7 (a) of the minutes of the eleventh meeting of the Drugs Technical Advisory Board held on the 9th May, 1950, and to say that the Government of India consider that the words 'prescription', 'compounding' and 'made up' have acquired, in relation to drugs, a

meaning well-known to all and sundry and that it is not necessary to define these expressions in the Drugs Rules. Any attempt to define the words might fall short of the mark and that in the absence of any definition in the statute itself, these terms will carry their ordinary dictionary meaning and no complications are likely to arise on that account. It is requested that this communication may kindly be placed before the Board at its next meeting and the views of the Board communicated to this Ministry in due course. I am to add that pending receipt of the views of the Board, publication of the proposed amendments to rule 65(1) and 65(3) of the Drugs Rules has been kept in abeyance.

ENCLOSURE S

COPY OF LETTER NO. F. 1-13/51-DS., DATED THE 14TH JUNE, 1951, FROM SHRI J. N. SAKSENA, B.A., UNDER SECRETARY TO THE GOVERNMENT OF INDIA, MINISTRY OF HEALTH TO THE SECRETARY, D.T.A.B., C/O. D.G.H.S., NEW DELHI.

SUBJECT :—*Drugs Rules,* 1945—*rule* 32 *of the—Amendment of.*

I am directed to say that although the intention is that imported drugs should satisfy the provisions regarding packing and labelling as well as the provisions regarding standards, rule 32 of the Drugs Rules, 1945, as it stands at present refers to packing and labelling only. It is considered that this omission should be rectified by amending rule 32 to read as follows :—

"32. *Packing, labelling and standards of imported drugs.*—No drug shall be imported unless it is packed and labelled in conformity with the Rules in Parts IX, X and Schedule F and conforms to the standards laid down in Part XII."

2. It is requested that the proposed amendment in the Drugs Rules may kindly be placed before the D.T.A.B. at its next meeting and the views of the Board Communicated to this Ministry in due course.

ENCLOSURE T

COPY OF LETTER NO. F. 1-14/50-DS., DATED THE 15TH JUNE, 1951, FROM THE UNDER SECRETARY TO THE GOVT. OF INDIA, MINISTRY OF HEALTH, TO THE SECRETARY, DRUGS TECHNICAL ADVISORY BOARD, NEW DELHI.

SUBJECT :—*Drugs Rules,* 1945—*Amendment to Schedule F of.*

I am directed to refer to paragraph 38 of the draft minutes of the eleventh meeting of the Drugs Technical Advisory Board, and to forward herewith copies of the letters given below. The Government of India are of opinion that in absence of any provisions for potency test and assay in B.P. 1948 for Injection of Adrenaline Tartarate, it is necessary that special provision in this respect should be made in the Drugs Rules. I am to request that the matter may be placed for consideration before the Drugs Technical Advisory Board at their next meeting along with copies of letters from the Governments of West Bengal and Punjab and the views of the Board communicated to this Ministry.

1. Letter No. Medl/2160/2D-50/50, dated the 9th May, 1951 from the Government of West Bengal.

2. Letter No. 457-3HB-51/II-2203, dated the 4th June, 1951 from the Government of Punjab.

COPY OF LETTER NO. MEDL/2160/2D-50/50, DATED THE 9TH MAY, 1951, FROM THE GOVT. OF WEST BENGAL TO THE GOVT. OF INDIA, MINISTRY OF HEALTH, NEW DELHI.

SUBJECT:—*Drugs Rules,* 1945—*Amendment to Schedule F of*—

With reference to your letter No. F. 1-14/50-DS(I) dated the 11th April 1951, I am directed to say that BP 1948 monograph on Injection Adrenaline Tartarate does not contain any provision for potency test and assay. The only way by which this can be checked for potency would be to submit the original powder from which the injections are prepared to physical test as given under Adrenaline B.P.

For the purpose of analysis, the finished products only *i.e.,* Injection Adrenaline Tartarate will be available in the market and not the powder Adrenaline. Drugs Inspectors will usually take for sample not more than 3 or 4 boxes containing 6 or 12 ampoules of ½ or 1 cc. and out of that Government Analyst can be supplied with 1 or 2 boxes. Physical test decribed under Adrenaline (Powder) cannot be applied to this small quantity of Injection Adrenaline Tartarate and Analyst has to depend on Bio-assay for checking the quantity. So, for practical point of view, special provision for potency test and Assay for Injection Adrenaline Tartarate, which is not covered by B.P. should be introduced.

I am, therefore, to request you to be so good as to consult the Drugs Technical Advisory Board on behalf of this Government for introduction of the above procedure and communicate their decision in due course.

COPY OF LETTER NO. 4457-3HB-51/II-2203, DATED THE 4TH JUNE, 1951, FROM THE GOVERNMENT OF PUNJAB TO THE GOVERNMENT OF INDIA, MINISTRY OF HEALTH, NEW DELHI.

SUBJECT :—*Drugs Rules,* 1945.—*Amendment to Schedule F of*—

With reference to Shri Saksena's letter No. F.1-14/50-DS., dated the 7th April, 1951, on the above subject, I am directed to say that in view of the fact that the B.P. 1948 specifications under Adrenaline are not as exhaustive as those laid down in Part VIII of Schedule 'F' of the Drugs Rules, 1945, it would appear to be highly desirable to retain such of the existing provisions under these rules as are not covered by the B.P. 1948, in respect of Adrenalinae Tartarate. I am, therefore, to request that the matter in regard to deletion of Part VIII of Schedule F of the Drugs Rules, 1945 may kindly be re-examined in consultation with the Drugs Technical Advisory Board.

ENCLOSURE U

COPY OF LETTER NO. 9083/A DATED THE 6TH MAY, 1950, FROM THE DIRECTOR, CENTRAL RESEARCH INSTITUTE, KASAULI, P.O. KASAULI RESEARCH INSTITUTE, TO THE SECRETARY, THE DRUGS TECHNICAL ADVISORY BOARD, THE DIRECTORATE GENERAL OF HEALTH SERVICES, NEW DELHI-3

With reference to your letter No. 9-8/50-DAB, dated 22-4-1950, I forward herewith a proposed amendment relating to the provisions for antivenom serum in the Drugs Rules Section L Para 5(1)(a).

"The potency of antivenon serum (antivenene) will be expressed as the neutralizing value of 1 c.c. of the finished product against the amount of dried venom (expressed in mgm.) of species of snake from which it has been prepared. The test venon will be dried to constant weight and maintained in this state under vacuum. The tests employed for estimation of potency will be such as would meet the approval of the licensing authority."

CENTRAL RESEARCH INST., KASAULI,
Dated 6-5-50.

(Sd.)
LIEUT.-COLONEL,
Director.

ENCLOSURE V

COPY OF LETTER NO. 77071-D/50, DATED 14-8-50 FROM DR. K. VASUDEVA RAO, PROVINCIAL DRUGS CONTROLLER, MADRAS, TO THE DRUGS CONTROLLER (I), D.G.H.S., NEW DELHI.

SUBJECT :—*Drugs—Drugs Act,* 1940 *and Madras Drugs Rules,* 1945—*Registration of patent and proprietary medicines—taking out manufacturing licence.*

It is observed from the statement showing details of disposal of applications received with samples for registration of Patent and Proprietary medicines at the Central Drugs Laboratory, Calcutta forwarded to this office every fortnightly that some of the manufacturers have registered their products but they are not in possession of manufacturing licences under Madras Drugs Rules, 1945. They are under the impression that the manufacturing licence is not necessary if their products are registered at the Central Drugs Laboratory. It is presumed that the Director, Central Drugs Laboratory is registering all the medicines irrespective of the fact whether the manufacturers are in possession in proper licences or not. If this procedure is allowed, it will defeat the purposes of Drugs Act and Rules.

It is therefore suggested that the Director, Central Drugs Laboratory may kindly be instructed to register only the medicines which are forwarded by the licensed manufacturers. Before registering, the manufacturers may be asked to state their manufacturing licence Numbers.

ENCLOSURE W

COPY OF LETTER NO. 04 M/D/633, DATED 4-11-50 FROM MR. S. P. SEN, CALCUTTA, TO THE SECRETARY, DRUGS TECHNICAL ADVISORY BOARD, NEW DELHI.

I would like to request you to put up in the next D.T.A.B. meeting whether the calculated strength of a certain ingredient in a preparation should be taken as the standard for the final product. To make the point clear it may be mentioned that B.P. '48 prescribing no strength for Acetic Acid content in Syrup Scillae although Acetum Scillae containing a known strength of Acetic Acid forms one of its ingredients. In the process of manufacture of the Syrup evidently there will be loss of acid content due to manipulation, specially when application of heat and straining have been prescribed. Now the question arises whether the Acetic Acid content, calculated from the formula of Syrup Scillae should form the standard of its acid content.

ENCLOSURE X

A COPY OF D.O. NO. SV/3812/A, DATED 1-3-1951 FROM THE DIRECTOR, CENTRAL RESEARCH INSTITUTE, KASAULI TO THE DIRECTORATE.

At the third session of the Expert Committee on Biological Standardization held in May 1949 it was decided that the I.U. for tetanus antitoxin will hencèforth be the same as the U.S.A. unit. The change was to take effect from 1st July, 1950.

As we obtain our supplies of standards for antitoxin sera from National Institute for Medical Research, London. I made enquiries from the Director of Department of Biological Standards regarding the steps taken in U.K. to implement the recommendations of the Expert Committee on Biological Standardization. I am attaching a copy of the reply received.

The change suggested is of fundamental nature and similar measures should also be taken in India to bring the labelling of tetanus antitoxin in conformity with the recommendations of the Expert Committee. I suggest that this may be included in the agenda for the next Drugs Technical Advisory Board meeting.

COPY OF LETTER DATED 29TH JANUARY, 1951 FROM THE DIRECTOR, DEPARTMENT OF BIOLOGICAL STANDARDS, NATIONAL INSTITUTE FOR MEDICAL RESEARCH, THE RIDGEWAY, MILL HILL, LONDON N.W. 7, TO THE DIRECTOR, CENTRAL RESEARCH INSTITUTE, KASAULI.

The recommendations of the Expert Committee on Biological Standardization of the World Health Organization held in May, 1949 about the new international unit for tetanus antitoxin, were approved by the World Health Assembly. In this country manufacturers have been informed that under the Therapeutic Substances Act they will be required to designate potency of tetanus antitoxin in 'international units (1950)' and to indicate that this unit is equal to 'two international units (1928)' and equivalent to the American Unit.

Although the change officially came into effect in July 1950 there will clearly be a period when manufacturers will be using up old labels and a certain latitude is allowed before a demanding the new labels, but the new system should be well under way by now.

A COPY OF LETTER NO. LSM/8963/51, DATED 18-1-51 FROM BENGAL IMMUNITY CO. CALCUTTA TO THE DRUGS CONTROLLER, DIRECTORATE GENERAL OF HEALTH SERVICES, NEW DELHI.

SUBJECT :—*International Unit of Tetanus Antitoxin.*

An International Standard was adopted in 1928 defining the International Unit of Tetanus Antitoxin as 0·1574 mg. Recently the Third Health Assembly of World Health Organisation recommended that all member States recognise the International Unit of Tetanus antitoxin as 0·3094 mg. so as to bring it into equally with U.S. National Institute of Health Unit.

(1) Cronicle of W.H.O., 4, No. 7-8 Aug. 1950.

(2) Sir S. S. Sokhey, Br. Med. Jr. May, 6 1950 pp. 1040.

We wrote to Central Research Institute, Kasauli but they could not inform us about the change in the absence of an official communication.

Will you kindly advise us about the present position of the International Unit of Tetatnus Antitoxin, so that we can take action if any is indicated.

With thanks.

EXTRACTS FROM CHRONICAL OF W.H.O. 4, NO. 7-8 AUG. 1950, PAGES 224-25.

* * * * *

International Biological Standards

The Third Health Assembly recommended that all member States recognize officially the international standards and units listed below :

International standard preparations	International units.
* * * * *	
Tetanus antitoxin	0·3094 mg.
* * * * *	
* * * * *	

It was also recommended that these standards and units be introduced into national pharmacopoeias to serve as a reference for assay. In those contries which do not possess a national pharmacopoeia the potency appearing on the labels of biological products should be expressed in international units.

EXTRACTS FROM SIR S. S. SOKHEY, BRITISH MEDICAL JOURNAL, MAY, 6. 1950, PAGE 1040.

* * * * *

The Committee considered the extensive use made both of International and U.S. National Institutes of Health units in designating the potency of tetanus antitoxin and reviewed the circumstances in which the international unit was defined in 1928. On the basis of an inquiry instituted in various countries it was decided to re-define the international unit for tetanus toxin so as to bring it into equality with the U.S. National Institute of Health unit. This change has been duly advertised, and as from July 1, 1950, the international unit for tetanus antitoxin will be the specific neutralizing activity for tetanus toxin contained in 0·3049 mg. of the standard preparation.

ENCLOSURE Y

COPY OF D.O. NO. SV/12501/A, DATED THE 28TH JUNE, 1951, FROM THE DIRECTOR, CENTRAL RESEARCH INSTITUTE, KASAULI, ADDRESSED TO MR. P. M. NABAR, CHIEF ADVISORY CHEMIST. DIRECTORATE GENERAL OF HEALTH SERVICES, NEW DELHI.

The following drugs under schedule F of the Drugs Rules, 1945 have been excluded from British Pharmacopoeia 1948.

Staphylococcus Antitoxin

Antidysentry Sera (Shiga) and other

Antidysentry Sera

Anti pneumococcus Serum (Type I)

Anti pneumococcus Serum (Type II)

You are well aware that due to the recent advances in Chemotherapy and Antibiotics these drugs no longer enjoy any popularity and are seldom if ever employed. I recommend that these drugs be also deleted from the Drugs Rules, 1945 and the matter placed on the Agenda of the Drugs Technical Advisory Board for its next meeting.

MINUTES OF THE TWELFTH MEETING OF THE DRUGS TECHNICAL ADVISORY BOARD HELD IN THE OFFICE OF THE DIRECTOR GENERAL OF HEALTH SERVICES, NEW DELHI, ON THE 17TH AND 18TH AUGUST, 1951.

Present:

(1) Dr. K. C. K. E. RAJA, Director General of Health Services (*Chairman*).

(2) Lt. Colonel M. L. AHUJA, Director, Central Research Institute, Kasauli.

(3) Dr. BALBHADRA MISRA, Behrampore, Orissa.

(4) Dr. U. P. BASU, Director, Bengal Immunity Research Institute, Calcutta-16.

(5) Dr. S. DUTTA, Director, Indian Veterinary Research Institute, Izatnagar (U.P.).

(6) Dr. B. N. GHOSH, Carmichael Medical College, Calcutta.

(7) Dr. J. C. GUPTA, Amherst Street, P.O. Calcutta.

(8) Dr. B. MUKHERJI, Director, Central Drugs Laboratory, 110-Chittaranjan Avenue, Calcutta.

(9) Dr. H. R. NANJI, Managing Director, ITALAB, Ltd., Fort, Bombay.

(10) Dr. P. K. SANYAL, Provincial Drug Control Laboratory, Calcutta.

(11) Dr. A. K. SEN, 45, Ballygunge Place, Calcutta.

(12) Shri S. P. SEN, Manager, Messrs. Bengal Chemical & Pharmaceutical Works, Ltd., Calcutta.

(13) Shri K. V. SUNDARAM AYYAR, 3, Jagadiswara Street, Thaiagarayangar, Madras-17.

(14) Shri P. M. NABAR, Drugs Controller, India, Directorate General of Health Services, New Delhi (*Member*) (*Secretary*).

1. Apologies for absence were received from Drs. B. N. Prasad and B. B. Dikshit.

Item 1 of the Agenda—Confirmation of the minutes of the eleventh meeting.

2. The minutes of the eleventh meeting were confirmed with the decision that the joint letter of Dr. A. K. Sen, Shri S. P. Sen and Dr. U. P. Basu be made an appendix to the minutes (Appendix I), that the Chairman take appropriate action on the points requiring action and that a brief note (Appendix II) be included in the minutes regarding the points raised by Shri K. V. Sundaram Ayyar in respect of his being debarred from attending the tenth meeting of the Board.

3. The Board desired that action in respect of item 6 of the minutes of the eleventh meeting of the Drugs Technical Advisory Board should be taken by the Government of India with the least possible delay.

4. The Board resolved that the minutes of the meetings of the Board should record only the decisions, arrived at by the Board and not the discussions leading the decisions, excepting where the Board specifically decides to have the proceedings recorded in detail.

5. The Board decided to extend the life of the two Sub-Committees appointed to investigate and report on (a) the Conditions of storage in regard to drugs specified in Schedules C and C.I. to the Drugs Rules, and (b) Poisons, by three years from November, 1951 and January, 1952 respectively. The Board also decided that the members of the Committees will act in their personal capacity and not in virtue of the offices they hold.

Item II of the Agenda—Consideration of the following questions arising out of the proceedings of the last meeting

6 (a) *Para 5 of the minutes*: *The question of fixing a life period for Cholera Vaccine* (*Enclosures A and B to the Agenda of the twelfth meeting*).—The Board decided that it was necessary to prescribe a limit of time for the use of Cholera Vaccine after its manufacture and recommended 18 months as that period.

(b) *Para 20 of the minutes* : *The minutes of the first three meetings of the Poisons Sub-Committee for consideration and approval* (*Enclosures X and Y to the Agenda of the tenth meeting and Enclosure C to the Agenda of the twelfth meeting*).—The minutes of all the three meetings were approved by the Board.

(c) *Para 21 of the minutes* : *Question whether injectible preparations of Ayurvedic and Unani Systems of medicines should not be controlled under the provisions of the Drugs Act* (*Enclosure D to the Agenda of the twelfth meeting*).—The Board considered that "Atomised Mica" in injectible form is a drug under the Drugs Act and Rules. It, therefore, recommended that all the provisions of the Act and Rules should be brought into operation by the Licensing Authority in regard to this drug. This was the unanimous view of the Board.

The Board by a majority of votes decided that "Atomised Mica" in injectible form is a "New Drug". Mr. Sundaram Ayyar, Dr. Gosh and Mr. Nabar held a different view. The Board also recommended as its majority view that such action as was contemplated, under the Rules, in respect of "New Drug" should be undertaken without delay.

(d) *Para 22 of the minutes* : *Reconsideration of Rule 65 (5) of the Drugs Rules* (*Enclosures E and F to the agenda of the twelfth meeting*).—(i) The Board recommended that manufacturers should be exempted from keeping separate registers of sale by way of wholesale dealing of drugs specified in Schedule C to the Drugs Rules 1945.

(ii) The Board after taking into consideration the objection raised by P A M D A L reiterated its previous recommendation to the Government regarding the amendment to Rule 65 (5).

(e) *Para 25 of the minutes* : *Regarding consideration of the question whether the additional harmless colouring matter in B.P. tinctures and spirituous preparations should be allowed or not* (*Enclosures G & H to the agenda of the twelfth meeting*).—The Board considered that the addition of colouring matters of an innocuous nature and in a manner not to reduce the therapeutic efficacy of the drug may be permitted within the limits prescribed by the Board. In the opinion of the Board the colouring substance to be used should be among those in a list to be approved by the Board. The label must contain the name of the colouring matter as well as the amount that has been used.

The Board appointed a Sub-Committee consisting of Dr. B. Mukherji, Dr. Nanji, Mr S. P. Sen, Mr. Sundaram Ayyar and Mr. Nabar to draw up a list of colouring material and to suggest permissible upper limits for each of them. The Committee was requested to report within six months. Mr. Nabar will also be the Secretary of the Committee.

In the period that intervenes before the suggestions put forward here are considered by the Central and State Governments and are brought into operation, the Board recommended that the following colouring materials be permitted for use :—

1. Caramel.
2. Amarnath Red.
3. Chlorophyll.
4. Naphthol Yellow S.

(f) *Para* 26 *of the minutes*: *Consideration of the letter dated the* 10*th February*, '50 *from Dr. Jivraj N. Mehta regarding relaxation of the provision for 'qualified persons' in the light of the remarks from the Pharmacy Council of India* (*Enclosure I to the Agenda of the twelfth meeting*).—The recommendations of the Pharmacy Council on the points raised by Dr. Jivraj N. Mehta in its letter No. 16-26/50-P.C.I. (D), dated the 15th March, 1951 to the Director General of Health Services was endorsed by the Board.

(g) *Para* 34 *of the minutes* : *Endorsement No.* 1-6/50-*DS dated the* 25*th April*, '50 *regarding introduction of provisions in Schedule F in respect of B. C. G. Vaccine* (*Appendix V to the minutes of the eleventh meeting*).—The Board appointed a Sub-Committee consisting of Dr. Ranganathan, Col. Ahuja, Dr. B. Mukherji, Dr. A. K. Sen and Mr. M. R. Dhanda to draw up standards in respect of B. C. G. Vaccine and have them submitted to the Chairman within six months. The Secretary of the Board will be a member and Secretary of the Committee.

(h) *Para* 36 *of the minutes*: *Consideration of letter No.* 29/50, *dated the* 27*th February*, '50 *from the All India Chemists and Druggists Federation. New Delhi* (*Appendix VII to the minutes of the eleventh meeting*) *suggesting that the sole agency clause for the import of Schedule C drugs should be done away with.*—The Board recommended that the Sole agency clause for the import of Schedule C drugs should stand with the proviso that it should be relaxed in respect of Aureomycine, Chloromycetin and Terramycine, so long as these drugs are not manufactured in the country.

Item III of the Agenda—Consideration of the communications received from the Government of India, Ministry of Health.

7. (1) *Letter No.* F. 1-9/48-D, *dated* 26-6-50—*Drugs Rules* 1945—*Amendment of sub-rule* (2) *of the Rule* 108-*Penicillin in single dose container* (*Enclosure J to the Agenda of the twelfth meeting*).—The Board decided that in regard to the aqueous preparations of Penicillin in multiple-dose containers the addition of an anti-septic equivalent to 0·5% of phenol is necessary. The question of Penicillin in oil and wax was kept pending receipt of particulars of the exemptions provided for by the U.K. authorities in this connection.

(2) *Letter No. F.* 1-7/50-*DS, dated* 18-8-50—*Amendment to the Drugs Rules,* 1945—*consideration of Dental Surgeons to be treated as registered medical practitioners* (*Enclosure K to the Agenda of the twelfth meeting*).—It was decided that the implications of the suggestion put forward by the Government of India should first be examined by Mr. Nabar.

(3) *Letter No. F.* 1/47-*D, dated* 17-8-50—*Amendment to the Drugs Rules* 1945—*Patent and Proprietary Medicines* (*Enclosure L to the Agenda of the twelfth meeting*).—It was decided to refer the letter from the Government of Madras to the Government of India, Ministry of Health, (No. 89532-GI/48-1 P.H. dated 24th January, 1951) with the enclosure, to the Analysts' Conference for consideration and report.

(4) *Letter No.* 2214-*DS*/50, *dated* 7-11-50—*Fixation of "Poison" labels on certain items* (*Enclosure M to the Agenda of the twelfth meeting*).—Mr. Nabar drew the attention of the Board to the recommendations of the POISONS Sub-Committee on this letter.

The Board accepted the recommendations of the Poisons Sub-Committee and decided that all the items mentioned in letter No. 04M/D/258 dated the 26th June, 1950, from the Manager, Bengal Chemical and Pharmaceutical Works Ltd., Calcutta, to the Drugs Controller, India, except 'Lotio Hydrarg Nigra', should be exempt from being labelled as 'Poison'. The Board recommended to the Government of India that early action be taken to communicate this recommendation of the Board to all State Governments.

(5) *Letter No. F*-1-13/50-*DS., dated* 13-12-50—*Labelling non-biological drugs not included in Schedule E* (*Enclosure N to the Agenda of the twelfth meeting*).—The Board having considered letter No. DLA-11-9/50, dated the 22nd August, 1950, from the Director of Health Services, West Bengal, Calcutta, to the Drugs Controller (India), decided to ask the West Bengal Government to supply the complete list of drugs in respect of which it is desired that labelling "For External Use Only" should be done.

(6) *Letter No. F.* 1-1/51-*DS, dated* 17-1-51. *Amendment of the Drugs Rules with a view to permitting the import of Schedule C & C.* (*1*) *drugs for personal use and for use in Missionary, Charitable and other institutions without import licences.* (*Enclosure O to the Agenda of the twelfth meeting*).—The Board considered carefully letter No. F. 1-1/51-DS, dated the 17th January, 1951, from the Government of India to the Secretary, Drugs Technical Advisory Board, suggesting certain amendments so as to permit the import of Schedule C. & C. (1) drugs for personal use or for use when received as free gift by missionary, charitable and other institutions. The Board considered that the draft amendment accompanying the above mentioned letter of the Government of India required modification and suggested that the form shown below should in substance be adopted by Government and put into proper legal form for incorporation in the Drugs Rules :—

"Such drugs under Schedules C. & C(1) as are not manufactured in the country and are required for personal use without forming part of *bona fide* personal baggage shall be permitted to be imported on a special licence subject to the following conditions :—

(i) The Licensing Authority is satisfied that the drugs if for *bona fide* personal use, and

(ii) the quantity of any single drug so imported shall not exceed one hundred average doses, provided that the licensing authority may in an exceptional case in any individual case sanction the import of a larger quantity.

Further, drugs under Schedules C. & C(1) shall be permitted to be imported by charitable, medical or research institutions on a special licence subject to the following conditions :—

(a) the licensing authority is satisfied that they are of standard quality and that a regular import licence cannot be obtained by the institutions mentioned above, and

(b) the drugs are received as free gifts and are used for the free treatment of genuine patients without any distinction of caste, creed or colour.

The above proposal was passed by a majority vote. Dr. A. K. Sen dissenting in respect of the recommendations relating to charitable, medical and research institutions.

(7) *Letter No. F. 1-9/51-DS, dated 8-5-51—Question whether sulpha drugs can be sold by unqualified persons (Enclosure P to the Agenda of the twelfth meeting).*—The Board considered letter No. 4121/33/9113-D, dated 17th March 1951 from the Government of Bombay to the Government of India and decided that retail sale of sulpha drugs can be made in original packing or in split packing only on the prescriptions of a registered medical practitioner and by or under the personal supervision of a qualified person.

(8) *Letter No. F. 1-19/50-DS, dated 12-5-51—Exemption regarding Epsom Salt prepared from sea water (Enclosure Q to the Agenda of the twelfth meeting).*—The Board considered letter No. F. 1-19/50-DS, dated the 12th May, 1951, from the Government of India, Ministry of Health, to the Secretary, Drugs Technical Advisory Board regarding amendment in Schedule 'K' in respect of exemption for limit of chloride content in Epsom Salt manufactured from sea water. The Board agreed, by a majority vote, to the upper limit of chloride content being fixed at 0·12%. The voting was as follows :—

For the motion	*Against the motion*
1. Dr. Nanji	1. Mr. Sundaram Ayyar
2. Dr. Dutta	2. Dr. A. K. Sen
3. Dr. Sanyal	3. Mr. S. P. Sen
4. Col. Ahuja	4. Dr. Gupta
5. Dr. Ghosh	5. Dr. Basu
6. Mr. Nabar	

It was also recommended that the label should be 'Magnesium Sulphate. B.P. or U.S.P. with chloride content not exceeding 0·12%'. The voting in respect of this decision was also the same as shown above.

It was further recommended that 'the magnesium Sulphate has been derived from sea water' be added.

(9) *Letter No. F. 1-12/48-D, dated 7-6-51—Rules 65(1) and 65(3)—Amendment of (Enclosure R to the Agenda of the twelfth meeting).*—The Board considered letter No. 1-12/48-D. dated 7th June, 1951 from the Government of India to the Secretary, Drugs Technical Advisory Board and appointed a Sub-Committee consisting of Dr. A. K. Sen, Dr. Gupta, Dr. Ghosh, Dr. Sanyal, Dr. U. P. Basu and Mr. S. P. Sen to frame definitions for the words "prescription", "compounding" and "made up" and any other term which may be desirable from the point of view of efficient working of the Drugs Act and the Rules.

Dr. Sanyal would be the convener.

The report should be submitted within three months.

(10) *Letter No. F. 1-13/51-DS, dated 14-6-51 Rule 32 of the Drugs Rules—Amendment of (Enclosure S to the Agenda of the twelfth meeting).*—The amendment suggested by the Government of India was agreed to.

(11) *Letter No. F. 1-14/50-DS, dated 15-6-51—Amendment to Schedule F to the Drugs Rules (Enclosure T to the Agenda of the twelfth meeting).*—The Board considered letter No. F. 1-14/50-DS, dated the 15th June, 1951, from the Government of India, Ministry of Health to the Secretary, Drugs Technical Advisory Board and appointed a Committee consisting of Dr. B. Mukerji, Dr. A. K. Sen and Dr. U. P. Basu to draw up suitable provisions for Injectio Adrenalin. Dr. Mukerji will be the convener.

Item IV of the Agenda—Consideration of the following communications.

8. (1) *Amendment relating to the provisions for Anti-venom Serum in the Drugs Rules-Section L para 5 (1) (a) as proposed by the Director, Central Research Institute, Kasauli (Enclosure U to the Agenda of the twelfth meeting).*—The amendment suggested by the Director, Central Research Institute, Kasauli, was agreed to by the Board.

(2) *Question whether form 3 in the Drugs Rules, 1945, should be amended so as to indicate that the applicant has got a licence to sell drugs (Enclosure V to the Agenda of the twelfth meeting).*—The Board considered that the task of enforcing the requirements of taking out a licence rests on the State Governments. The Secretary should make it clear to the Drugs Controller, Madras, that the taking out of a manufacturing licence by any person prior to the submission of a request for registration of a patent or proprietary medicine is not necessary.

(3) *Letter No. 04 M/D/633 dated 4-11-40 from Mr. S. P. Sen, a member of the Drugs Technical Advisory Board. Standard for final product (Enclosure W to the Agenda of the twelfth meeting).*—The Board decided to refer the matter to the Indian Pharmacopoeia Committee with a request that standards be laid down wherever possible. The Board further decided to refer the matter to the Analysts' Conference to be held in the near future. In the meantime the Board pointed out that, where no standards in respect of final product are laid down in the B.P., it is desirable that State Authorities should not prescribe and enforce standards on their own.

(4) *D.O. Letter No. SV/3812/4, dated 1-3-51, from the Director, Central Research Institute, Kasauli—standard for Tetanus anti-toxin (Enclosure X to the Agenda of the twelfth meeting).*—The Board decided to adopt the International Standards and Units for tetanus Antitoxins as approved by the World Health Organization. Consequential changes should be carried out in the Drugs Rules.

(5) *D.O. Letter No. SV/12501/A, dated 28-6-51 from the Director, Central Research Institute, Kasauli—suggestion to exclude certain items from Schedule F of the Drugs Rules (Enclosure Y to the Agenda of the twelfth meeting).*—The Board did not agree to the suggestion.

Item V of the Agenda—Any other business.

9. *A note by Dr. Nanji with regard to the labelling provisions in the Drugs Rules was circulated to the members (Appendix III).*—The Board recommended the insertion of a new Rule 96-A, reading as follows :—

"96-A. *Labelling of Drugs.*—The container of a drug shall be labelled with :

(a) name and quantity of the drug.

(b) name and address of the manufacturer".

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

APPENDIX I

Copy of joint letter dated nil from Drs. A. K. Sen, U. P. Basu and Shri S. P. Sen, Calcutta to the Secretary, Drugs Technical Advisory Board.

With reference to your letter No. 9-13/50-D, dated the 7th June, 1950 along with the draft minutes of the eleventh meeting of DTAB we beg to submit our comments as under :—

Paragraph 5(4) *of the Minutes—pp.* 2-2(c) :

Only the question of licence for manufacture by the Government Institutions has been mentioned. But in addition to the resolution taken by the Board in a previous meeting that the Government Institutions manufacturing Drugs would require licences just like private institutions, another decision also was taken by the Board that Government Institutions engaged in Drug manufacturing activities should not be made the testing authorities of these drugs, and thus the C.R.I. Kasauli, Haffkine Institute, Bombay and Guindy Institute, Madras could not be testing authorities of vaccines and sera. In view of this decision the Board recommended to the Central Government to furnish the Central Drugs Laboratory with necessary apparatus and equipments so as to enable it to undertake testing of vaccines and sera as early as possible. The Secretary was requested to submit a note on this point also as regards the position of this resolution and if a copy of the resolution has been forwarded to the Central Government with proper advice.

While on the subject of Vaccine & Sera manufactured by Government Bodies, a label of Cholera Vaccine manufactured by the Bengal Government was placed before the Board. The label did not contain the date of manufacture, units per c.c., the licence number and any address of the Laboratory. The Board took a serious view of the thing and the Chairman asked the Secretary to write to the Bengal Government pointing out to them that it was in contravention of the specific provisions of the Drugs Act and Rules.

Pp. 3 *after item* 5 :

Dr. U. P. Basu raised the question as to whether the DTAB could prescribe any time limit for TAB vaccines without modifying the Drugs Act as the Drugs Act has accepted 'the latest edition of the British Pharmacopoeia' as the standard for drugs and as in this Pharmacopoeia there is no mention of time limit.

The Chairman directed the Secretary to take legal opinion on the subject pending which the decision for the life period of other vaccines be deferred.

Pp. 6 *para* 12 :

The opinion of Mr. Nabar only has been recorded. It is felt that the other side also should have got some mention. The consensus of opinion was that since India is producing B.P. quality Magnesium Sulphate in sufficient quantities to meet the demand of the country and to spare, there is no occasion to lower the standard of Mag. Sulphate for medicinal purposes. Emergency question might be discussed on emergent occasions. A contraversy

:o arose as to the reactivity of the presence of chloride being harmful to : human system, when Mr. Nabar withdrew his letter. The Board, how-r, decided that if Messrs. Tata Ltd., desired to secure any exemption n the standard prescribed in the Drugs Act, they should approach the rd through the State Government.

Was really a decision taken that the standard of Magnesium Sulphate : marine sources should be decided by the Indian Pharmacopoeia Com-.ittee ?

Pp. 7 :

On the formation of a new sub-committee on Bacteriophage a question was raised as to how many sub-committees have up-to-date been formed, ow many sittings of those sub-committees been held and if the sub-committees submitted any reports of their meetings. The Secretary told the Board that he would compile a statement and send it to the individual members. The Chairman accepted the Secretary's submission.

Pp. 9, *item IV of the agenda* (2)—*pp* 22 :

"The amendment was actually modified after elaborate discussion and the modified amendment was passed and not the amendment as it is. The modification was by the insertion of the words "excluding manufacturers" between "Schedule C" and "shall be recorded etc." and that the modified amendment read as follows :

All purchases and sales by way of wholesale dealing of drugs specified in Schedule C, "excluding manufacturers" shall be recorded in a register, etc., etc.

It was also decided that register should be properly defined".

Pp. 10(2) :

It was only on Dr. Sen's point that the Drugs Act and Rules did not prohibit the use of harmless and inert colouring matter, that the legal opinion was to be sought for, but on the technical side of the question a definite decision was taken that "the Board decided that the use of such innocuous and harmless colouring matter, indicated in the BPC such as Caramel, etc., may be allowed". Whereupon incidentally two important questions arose :

(1) whether U.P. Government could issue such a Press Note without consulting the D.T.A.B.; and

(2) whether any State Government could issue Gazette Notification or Press Notes making amendments of the Drugs Rules without consulting DTAB as the Bombay Government had done by asking the manufacturers to put the spirit strength on the labels of the spirituous medicinal preparations, though the Drugs Act and Rules provide that if a Drug is declared B.P. no other indication need be put on the label. Mr. Nabar supported the Bombay Governent on the plea of prohibition, but the Board decided that the actions of both the Governments of U.P. and Bombay were not in keeping with the Drugs Act and the Secretary was asked by the Chairman to write to the respective Governments pointing out their defects.

The careful and correct recording of the proceeding is an essential part of meeting. Such omission and commissions are disadvantageous in more ways than one. We hope, therefore, that steps should be taken to record the minutes in the way they are discussed in the meeting.

Thanking you.

APPENDIX II

Mr. K. V. Sundaram Ayyar, who was Government Analyst, Madras, was nominated in June 1949 by the Government of India as a member of the Drugs Technical Advisory Board under Section 5(2) (vi) of the Drugs Act. In December, 1949, when the notice and agenda of the tenth meeting of the Board were sent to him, he intimated to the Secretary, Drugs Technical Advisory Board, that he had retired from his post of Drugs Analyst under the Government of Madras and that he was, therefore, of the opinion that he had ceased to be a member of the Board. The Government of India, who were informed about this, wrote to the Government of Madras that Mr. Sundaram Ayyar had ceased to be a member of the Drugs Technical Advisory Board on retirement from service and asked that the State Government should ask for his resignation. In these circumstances Mr. Sundaram Ayyar did not attend the meeting of the Board held in February, 1950.

It was subsequently represented by Mr. Sundaram Ayyar that in accordance with Section 5 (3) of the Drugs Act, he could continue to be a member of the Board for the full term. The case was examined by the Ministry of Health in consultation with the Ministry of Law and it was decided that Mr. Sundaram Ayyar would continue to be a member of the Board for three years from the date of his nomination, notwithstanding the fact that he ceased to be a Government Analyst. Since then he has been attending meetings of the Drugs Technical Advisory Board.

Mr. Sundaram Ayyar expressed regret that the necessary legal consultations were not held on the first occasion and that this resulted in his being debarred from attending the meeting of the Board in February, 1950. He desired that, in order to prevent a recurrence of such an event, a brief reference should be made in the minutes to this incident.

APPENDIX III

There is at present no provision in the Drugs Rules for the labelling of drugs, which are not patent or proprietary medicines, or Schedule C drugs, with—

(a) name and quantity of the drug ;

(b) name and address of the manufacturer.

Thus, at present, anyone manufacturing or importing say Tinct. Card. Co., need not state the above particulars on the label of the container or on the packing in which the container is enclosed.

This lacuna in the Drugs Rules ought to be remedied. Moreover the Merchandise Marks Act will be enforced as from January, 1952. Some of the provisions of this Act conflict with the labelling provisions under the Drugs Rules. Representations have been received from several parties that the labelling provisions under the Merchandise Marks Act should not be made applicable to drugs as these are already covered by the labelling provisions under the Drugs Rules.

As pointed above, the Drugs Rules at present do not provide for the giving of the above mentioned particulars on the labels. It is considered that those should be provided for in the Drugs Rules not only to remove a lacuna in the Drugs Rules but also to make the labelling of drugs independent of the Merchandise Marks Act.

Suitable amendments in the Drugs Rules will be made if the D.T.A.B. agrees with the above view.

GIPX—S2—1 M of Helth/58 (12th Meeting)—1-1-60—400