GOVERNMENT OF INDIA

MINISTRY OF HEALTH

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

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AGENDA FOR THE ELEVENTH MEETING OF THE DRUGS TECHNICAL ADVISORY BOARD

I. Confirmation of the minutes of the tenth meeting.

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

(a) Amendments to Rules 65(1) and 65(3) as proposed by the Government of India, Ministry of Health, in their letter No. F. 1-12/48-D dated 11th February, 1949 (Enclosure F to the agenda of the tenth meeting).

(b) Amendments to the proviso to clause (4) of rule 65 as proposed by the Government of India, Ministry of Health, in their letter No. F. 1-15/49-D, dated the 19th January 1950 (Enclosure Q to the agenda of the tenth meeting).

(c) Letter dated 6th February, 1950 from Dr. K. A. Hamied, (Appendix II to the minutes of the tenth meeting).

III. Consideration of items Nos. IV and V of the agenda of the tenth meeting of the Board.

IV. Consideration of the following communications received from the Government of India :—

(1) Letter No. F. 11-14/50-DS, dated 9th February 1950 (Enclosure A) regarding the question whether injectible preparations of Ayurvedic and Unani systems of medicine should not be controlled under the provision of the Drugs Act.

(2) Letter No. F. 1-20/49-DS, dated 10th February 1950 (Enclosure B) regarding the amendment of Rule 65(5) of the Drugs Rules, 1945 in connection with maintenance of records of purchases and sale by way of wholesale dealing of Schedule C drugs.

(3) Letter No. F. 10-21/49-DS, dated 13th March 1950 (Enclosure C) regarding amendment of the Drugs Rules in respect of the sale of drugs by *itinerant* vendors, grocers, *pan-supari* shops, etc., etc.

V. Consideration of the following :—

(1) Letter dated 27th December 1949 from Shri K. V. Sundaram Ayyar, Madras. (Enclosure D.)

(2) Letter No. 217, dated 6th February 1950 from the Indian Chemical Manufacture's Association. Calcutta and letter dated 9th February 1950 from the U. P. Pharmaceutical Manufacturer's Association, Lucknow (Enclosure E) regarding the use of harmless colouring matter in B. P. tinctures and spirituous preparations.

(3) Letter dated 10th February 1950 from Dr. Jivraj N. Mehta, Bombay regarding the need for relaxing the provisions for "qualified person" in the Drugs Rules. (Enclosure F.)

(4) Consideration of amendments to the provisions relating to vaccine Lymph in the Drugs Rules as suggested by the I.R.F.A. (Enclosure G.)

VI. Consideration of suggestion that a new rule reading as follows, may be inserted between rules 30 and 31 of the Drugs Rules, 1945:

"30A. Prohibition of Import of certain drugs.—No drug the manufacture, sale or distribution of which is restricted or prohibited in the country of origin shall be imported under the same name or under any other name."

VII. Any other business allowed by the Chairman.

ENCLOSURE A

COPY OF LETTER NO. F. 11-14/50-DS, DATED THE 9TH FEBRUARY, 1950, FROM THE GOVT. OF INDIA, MINISTRY OF HEALTH, TO THE SECRETARY, DRUGS TECHNICAL ADVISORY BOARD, C/O. DIRECTORATE GENERAL OF HEALTH SERVICES, NEW DELHI.

SUBJECT :—*Injectible preparations of Ayurvedic and Unani medicines-question of control under the Drugs Act and Rules.*

I am directed to forward herewith an extract from the report of the meeting of the Therapeutic Trials Sub-Committee of the Clinical Research Advisory Committee of the I.R.F.A. held in New Delhi on 23rd November, 1949 and to say that the same may be placed before the Drugs Technical Advisory Board at its next meeting and the views of the Board communicated to this Ministry in due course.

EXTRACT FROM THE REPORT OF THE MEETING OF THE THERAPEUTIC TRIALS SUB-COMMITTEE OF THE CLINICAL RESEARCH ADVISORY COMMITTEE OF THE I.R.F.A. IN NEW DELHI ON 23RD NOVEMBER, 1949.

* * *

3. To consider whether clinical trials of Ayurvedic and Unani medicines be undertaken by the I. R. F. A.

The Sub-Committee decided that clinical trials should be undertaken of only those Ayurvedic and Unani medicines whose composition or derivation was from a single plant or from a single mineral ingredient and that in the case of those medicines with combined substances, such clinical trials will be considered on the merits of each preparation. The sub-committee also recommended that in view of the fact that medicines prepared under the Ayurvedic and Unani systems are supposed to be for oral treatment not in the form of injections, any injectible preparation of these medicines should come under the control of the relevant section of the Drugs Act. The sub-committee recommended that this suggestion be brought to the notice of the Drugs Technical Advisory Board of the Government of India.

ENCLOSURE B

No. F. 1-20/49-DS.

GOVERNMENT OF INDIA.

MINISTRY OF HEALTH.

New Delhi, the 10th February, 1950.

FROM

J. N. Saksena, Esquire, B.A.,

Under Secretary to the Government of India,

To

The Secretary to

(ALL STATE GOVERNMENTS)

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

SIR,

I am directed to invite the attention of the State Government to sub-rule (5) of rule 65 of the Drugs Rules, 1945 which lays down that records shall be maintained of all purchases and sales by way of wholesale dealing

of drugs specified in Schedule C and such records shall include certain particulars. A question has been raised whether invoices, if they contain the prescribed particulars, can be considered as records or maintenance of registers is necessary for the purpose of the sub-rule. The matter was considered by the Drugs Consultative Committee at its first meeting (*vide* para. 18 of the minutes—copy forwarded with this Ministry's letter No. F.-4-1/49-DS, dated the 10th June 1949) which recommended that necessary amendments should be made in rule 65(5) so as to make it incumbent upon all importers and wholesalers to maintain registers for the purpose of the sub-rule. The Government of India propose to amend the Rules accordingly, as in the attached draft notification.

I am to enquire whether the State Government agree to the Drugs Technical Advisory Board being consulted for the purpose of amending the Provincial Drugs Rules on the same lines.

If the State Government agree, the Central Government will consult the Drugs Technical Advisory Board on behalf of itself and the State Government and communicate to the State Government the views of the Board. Further action for the amendment of the Central and Provincial Rules can be taken after the views of the Board are obtained. As the next meeting of the Drugs Technical Advisory Board is going to be held on the 20th February, 1950, the State Government are requested to send their reply in the matter at a very early date.

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

No. F. 1-20/49-DS.

GOVERNMENT OF INDIA.
MINISTRY OF HEALTH.

New Delhi, the 10th February, 1950.

Draft Notification

The following draft of a further amendment to the Drugs Rules, 1945, which it is proposed to make in exercise of the powers conferred by sections 12 and 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 ..... 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 Amendment

In rule 65 of the said Rules, for sub-rule (5) the following sub-rule shall be substituted, namely :—

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

(a) the dates of purchase and sale ;

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

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

(d) the name of the manufacturer ;

such record shall be preserved for three years from the date of the sale of the drug."

No. F. 1-20/49-DS.

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

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

ENCLOSURE C

COPY OF LETTER NO. F. 10-21/49-DS, DATED THE 13TH MARCH, 1950, FROM THE GOVT. OF INDIA, MINISTRY OF HEALTH, TO THIS DIRECTORATE.

SUBJECT :—*Drugs Rules* 1945—*Amendment of—in regard to the sale of drugs itinerant vendors and by Grocers, Pan-Supari Shops etc.*

I am directed to refer to this Ministry's letter of even number dated the 18th January, 1950 on the subject mentioned above, and to say that replies have been received from all State Governments agreeing to the proposals contained therein.

In this connection, I am to forward a copy of the letter from the Government of Bombay, No. 4121/33/2693-H, dated the 27th February, 1950 (with enclosure) communicating the views of the Drugs Controller, Bombay.

SUBJECT :—*Drugs Rules,* 1945—*Amendment of—in regard to the sale of drugs by itinerant vendors and by Grocers, Pan-supari shops etc.*

With reference to your letter No. F. 10-21/49-DS, dated the 12th January, 1950, on the subject mentioned above, I am directed to state that the Government of Bombay agrees to the Drugs Technical Advisory Board being consulted in regard to the proposed amendment of the Drugs Rules for prohibiting the sale of drugs by itinerant vendors and grocers, *pan-supari* shops etc. I am in this connection to forward a copy of letter No. D. C. 1/1463, dated the 16th February, 1950, from the Drugs Controller for the State of Bombay and to request that the fact mentioned in the letter may also be considered.

COPY OF AN EXPRESS LETTER NO. D.C. 1/1463, DATED THE 16TH FEB., 1950, FROM THE DRUGS CONTROLLER FOR THE STATE OF BOMBAY, TO THE SURGEON GENERAL WITH THE GOVERNMENT OF BOMBAY, BOMBAY.

SUBJECT :—*Drugs Rules, Amendment of—in regard to the sale of drugs by itinerant vendors and by Grocers Pan-supari shops etc.*

Reference your endorsement No. S. 228/5158-B, dated the 1st February, 1950.

I have the honour to submit my remarks on this important question of licensing of *itinerant* vendors, and grocers and *pan-supari* shops.

The Drugs Act has been enforced for the purposes of seeing that only drugs of standard quality are made available to the public. It is, therefore, necessary that drugs should be sold only at licenced premises and by persons who are literate and qualified to handle them.

Even, as such, on account of lack and necessary staff spurious drugs and sub-standard drugs are sold by so called walking chemists "vendors" and grocers and *pan-supari* shops, who are not licenced to sell stock or distribute drugs.

In the Drugs Rules the poisons and preparations containing poisons have been differentiated in Rule 65. The proviso to Rule 65(2) permits the sale of a preparation containing a drug specified in Schedule E by an unqualified person, if the preparation has been made up for sale elsewhere than on the premises and the container has not been opened since the time when the preparation was made for sale therein. This proviso therefore permits the sale of preparations containing poisons by unqualified persons and licensing of itinerant vendors, grocers and pan-supari shops will result in free sale of poisonous preparations, and encourage self medication to the detriment of public health. It will also make the work of control over the quality very difficult.

This differentiation between a poison and preparation containing a poison is not in keeping with the spirit of the Act. The way the Schedule E has been drawn up it is quite evident that an unqualified reference to a poison in Schedule E includes a reference to preparation containing that poison since varying control for certain poisons according to the proportion present is provided. This proviso to Rule 65(2) should therefore be deleted as it permits the sale of preparation containing poisons by unqualified persons. Only qualified persons should be permitted to deal in poisons.

The stocking, selling, dispensing or compounding of poisons should always be the privilege of a pharmacist. The amendment to the explanation of Rule 65(15) is already under consideration, by which a registered pharmacist only will be considered as a qualified person for the purposes of Rule 65.

Even in the minutes of the Drugs Consultative Committee it has been stated :—

> "The Committee would, therefore, stress the importance of making the premises for the distribution and sale of drugs the basis for control. It is, therefore, of the opinion that the general granting of licences to itinerant vendors and all kinds of shopkeepers will not be in the interest of efficient drug control. It is at the same time recognised that existing conditions might make it impossible to promote the distribution of drugs, solely through the licenced premises complying with the requirements of the Drugs Act and Rules in certain parts of the country particularly in sparsely populated areas. In such areas even distributing agencies such as itinerant vendors may be necessary the Committee however, desires to urge on the Provincial Governments the importance of ensuring that such agents are employed only in areas where their utilisation is absolutely necessary".

The premises where drugs are sold are important and therefore it is absolutely necessary to define 'Premises' in the Drugs Rules in order to enable the licensing authorities to refuse licence if the premises are not suitable and adequate for sale of drugs.

The distribution, retail sale, dispensing and compounding of drugs including Scheduled poisons should be restricted only to licenced premises at which the sales are conducted by or under the personal supervision of qualified persons. There is no necessity to relax this requirement in case of cities and towns as sufficient number of licenced premises exist. In such places the grocers, cloth merchants, hardware merchants, stationers, restaurants, panwallas and bidiwallas must not be licenced for sale of drugs, in Form 20 and 21. To meet the shortage of qualified persons it may be necessary to show some relaxation in the beginning by allowing all persons engaged in the sale of drugs to get qualified by passing an examination in Dispensing and Forensic Pharmacy within a specified period. The relaxation necessary can be decided upon by the licensing authority.

For the convenience of the public restricted licences may be issued for sale of non-poisonous house-hold remedies in packed containers. At such premises the selling of 'loose' drugs; compounding or dispensing; the receipt of prescription and the distribution of medicines compounded or dispensed for the needs of a particular person; and the use of certain titles specified in Rule 65(15) should be prohibited. The number and distribution of such shops can be decided by the licensing authority with due regard to the area of the place and the population to be served thereby.

Restricted licences in Form 20A as suggested in the draft notification may be issued subject to the discretion of the licensing authority in places where no chemists shops exist within a radius of say 5 miles, to enable the public to get supply of drugs.

The licences to itinerant vendors should be granted only in exceptional circumstances as stated in Rule 62-A(b) of the draft. It will be necessary to define the word "Itinerant Vendor" in the Drugs Rules.

I have expressed the above opinion keeping in view the recommendations of the Drugs Consultative Committee quoted above. Issue of restricted licenses without putting any limitations as to the circumstances in which they should be issued is likely to increase the sale of spurious and adulterated drugs, which should not be permitted in the public interest.

I am of the opinion that the State Government should agree to the Drugs Technical Advisory Board being consulted on this problem, which should take the above facts into consideration while arriving at a decision on this very important issue.

Accompaniments to your endorsement are returned herewith.

ENCLOSURE D

COPY OF D.O. DATED THE 27TH DECEMBER, 1949, FROM SHRI K.V. SUNDARAM AYYAR, M.SC., F.R.I.C., GOVERNMENT ANALYST (DRUGS), KING INSTITUTE GUINDY, MADRAS, ADDRESSED TO THE (CHIEF ADVISORY CHEMIST), SECRETARY, DRUGS TECHNICAL ADVISORY BOARD, DIRECTORATE GENERAL OF HEALTH SERVICES, NEW DELHI.

I am writing this letter to you on the eve of my retirement from service as Government Analyst (Drugs). I believe the position would be that I now cease to be a member of the Drugs Technical Advisory Board.

It was my ardent desire to participate in the next meeting of the Board and help the deliberation with my experience of the working of the Act and Rules for two years in the Madras Presidency. I have also studied the working of the Acts in England, U. S. A., France and Switzerland, as when I was on deputation in 1945-46. I was also associated closely with Mr. H. Hawley, my predecessor in office and who was a member of the Committee together with the late Dr. S. Rajgopal Naidu. The matter of the working of the Act and Rules is so complex, that it would tax the utmost of those who are called upon to work it. In fact Dr. Rajagopal Naidu was emphatically of the opinion that the Act and the Rules were unworkable and not in the best interests of the country and wanted its indefinite postponement. Mr. Hawley also withdrew from the Committee, if I remember right at the later stages.

I would like to draw the attention of the Committee in my official capacity as a Member of the Board, that for the proper functioning of the Act and the Rules, the relation between the Government Analyst and the Inspector and the Provincial Licensing Authority should be defined. Drug Controllers are being appointed by some Provinces but their functions have not been defined. As a Government Analyst appointed under the Act and Rules I desire to state that there should be more co-ordination between the Inspector and the Analyst and the Government Analyst should be consulted by the Provincial Drug Controller, on all matters regarding prosecutions and especially when a prosecution is proposed not to be launched as a result of the explanation given by a manufacturer bearing on the analytical result of the Government Analyst. The role of the Government Analyst (Drugs) and the Public Analyst has been well brought about by Mr. Liverseege, in his work on the "Adulteration and analysis of foods and drugs" and represents the current practice in the United Kingdom. The Public Analyst is a Statutory officer who is required to be highly and specially trained for his work and the best arrangement is that he should be responsible for the Administration of the Act in consultation with the Chairman of his Committee.

Letters to caution offenders are best sent by the Public Analyst. The replies to them are, at times, highly technical and a Medical Officer of Health, who sends such letters may become involved in a correspondence which he cannot continue without considerable help from the Public Analyst and which when half finished, he may even pass on that officer. This is the practice that has been adopted for the last 25 years as regards the administration of the Madras Prevention of Adulteration (Foods) Act. The sampling officers are under direct and constant touch with the Government Analyst and it has been found that it is the best method that could be arranged to efficiently and satisfactorily work the Act.

In Madras, in respect of cases under the Madras Prevention of Adulteration Act (Foods) for which I am also the Government Analyst, the direction of the Government is that prosecutions should be invariably launched when the Government Analyst issues a certificate of adulteration, leaving the Court to decide on the issues involved both on matters of fact and legal points. But the present rules or administrative practice obtaining, as regards the Drug Rules, do not allow these.

I am also of the opinion that there should be not interference whatsoever, in the analyst's work by the authorities *i.e.*, his independence should be preserved, as it obtains in England and U.S.A. There should also be a

provision in the Drugs Rules that at least an Annual Report should be submitted to Government by the Drugs Controller and the Government Analysts on their respective work. All that is now required under the Rules is that :

> "A Government Analyst shall from time to time forward to Government reports giving the result of analytical work and research with a view to their publication at the discretion of Government."

As a member of the Board, I request that this letter be placed before the Board for their consideration.

ENCLOSURE E

COPY OF LETTER NO. 217, DATED THE 6TH FEBRUARY, 1950, FROM THE SECRETARY, INDIAN CHEMICAL MANUFACTURERS' ASSOCIATION, CALCUTTA, TO THIS DIRECTORATE.

SUBJECT :—*Use of Caramel in Tinctures.*

The attention of the Committee of the Association has been drawn to a Press Note dated the 14th December, 1949 issued by the Information Directorate, U. P., warning drug manufacturers against the use of Caramel in Tinctures. A copy of the Press Note is enclosed for your ready reference.

It is felt by the Committee that a clarification on this matter is necessary as the British Pharmacopoeia does not lay down specific instructions on the use of Caramel in several tinctures. As a general rule, the addition of innocuous substances is not objectionable as for example, the addition of pure sodium chloride in injectables. The use of Caramel in tinctures is to maintain a uniform colour to a batch of particular tinctures. Crude vegetable drugs obtained from different sources and collected, dried and stored in different conditions and periods are bound to give different shades to Galenicals prepared from them. It is therefore felt necessary to standardise the colour by the addition of small quantities of Caramel.

As the press note of the U. P. Information Directorate raised a very important point affecting the drug industry, the Committee feel that a ruling is necessary on this matter from the Drugs Technical Advisory Board. The Committee shall therefore be thankful if you kindly place this matter before the next meeting of the D. T. A. B. and obtain the necessary clarification on the addition of Caramel to tinctures.

COPY OF LETTER DATED THE 9TH FEBRUARY, 1950, FROM THE SECRETARY U. P. PHARMACEUTICAL MANUFACTURERS' ASSOCIATION, LUCKNOW, TO THIS DIRECTORATE.

SUBJECT :—*Ban of the addition of caramel and other edible colour to the Pharmaceutical preparation by the Uttar Pradesh Government.*

In a recent press notification the Uttar Pradesh Government has banned the use of caramel in Tincture or other Galenicals. Their contention is that since the B. P., U. S. P. or B. P. C. etc. do not specifically mention such addition in individual monographs it is objectionable.

My Association contends that the addition of caramel to some of the galenicals particularly the light coloured ones is not only not objectionable but is definitely necessary for the following reasons:

1. Crude Drugs of vegetable origin are collected from different sources, dried and stored under varying conditions and for varying period before use

in galenicals. They therefore produce galenicals (Particularly those of light colour) of different shades. If two such bottles from two different batches are purchased by a medical practitioner an unhappy suggestion is made in his mind. It is, therefore, necessary for a manufacturer to standardise the colour of his finished preparation by addition of traces of harmless edible colouring agents.

2. Caramel is officially recognised in Indian Pharmacopoeal List 1946 and in the B. P. C. 1949 (Saccharum Ustum) as a colouring agent.

3. The monographs in the pharmacopoeias do not give all the minute details of manufacture. They give mere rough outlines. They generally give only one of the alternative methods of manufacture. They leave the details to be filled up by the manufacturer and give sufficient scope to his talents to improve upon the process and make his finished product as elegant as he can provided the main and active constituents are retained in the correct proportion and strength.

4. The difference in the colours of crude drugs is recognised in the B. P., *e.g.* Belladonna leaf "green or brownish green" Belladonna root 'internally, whitish to brownish" Hyoscyamus* green or "greyish-green Ipecac:— C Ipecac dark brick red to very dark brown" C. Acuminate "external surface greyish brown or reddish brown" Ipecac pulv "light grey to yellowish brown", etc. etc. Besides these differences the percentage of alkaloidal content also vary. All these factors give finished preparations of considerably different shades. The shades has to be standardised by addition of harmless and edible colours such as the official caramel.

5. The practice of standardising the colour of galencials is followed not only by Indian Manufacturers but to our knowledge in a stricter form by the foreign manufacturers. Hardly do we come across the preparation of a reputable foreign manufacturers differing from batch to batch in the slightest measure.

I would request you to give this matter an urgent attention and let me know the view of your committee.

Thanking you in anticipation.

ENCLOSURE F

SECRETARIAT

Bombay-1, 10*th February*, 1950.

MY DEAR RAJA,

I would refer you to Rules 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 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 &c. 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, Pharmachist &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 rule. 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 nameplate of chemists, pharmacist &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.

I understand that these questions were discussed at the Indian Pharmaceutical Conference held at Poona last month. The resolutions passed at this Conference, whose makers would naturally be anxious to maintain a high standard, would also need careful consideration.

Yours sincerely,

(Sd.) JIVRAJ N. MEHTA.

ENCLOSURE G

COPY OF LETTER NO. 8-47/49-DAB, DATED THE 7TH JANUARY, 1950, FROM THIS DIRECTORATE TO DR. C. G. PANDIT, D.P.H., PH.D., SECRETARY, INDIAN RESEARCH FUND ASSOCIATION, NEW DELHI.

SUBJECT :—*Provision for Vaccine Lymph in the Drugs Rules.*

With reference to paras 2, 3, 4 and 5 of the proceedings of the meeting of the sub-committee appointed to prescribe a standard technique of testing Anti-Smallpox Vaccine Lymph held on August 13, 1949 (extracts enclosed), I am to request that you will kindly let me have your suggestions regarding the specific amendments that may be made in the provisions for Vaccine Lymph in the Drugs Rules, 1945 in the light of the proceedings of the meeting. A copy of the Drugs Rules is herewith sent. This may please be returned with your reply.

COPY OF AN EXTRACTS FROM THE PROCEEDINGS OF THE MEETING OF THE SUB-COMMITTEE APPOINTED TO PRESCRIBE A STANDARD TECHNIQUE OF TESTING ANTI-SMALLPOX VACCINE LYMPH HELD ON AUGUST 13, 1949, IN ROOM NO. 88 (GROUND FLOOR), CENTRAL SECRETARIAT, NORTH BLOCK, NEW DELHI.

2. The sub-committee considered some of the provisions of the Rules framed under the Drugs Act India (1940) and felt that the standard of 20,000 viable organisms per c. c. (20 per milligram) prescribed for the plate count is capable of improvement. Some of the vaccine institutes in India were able to attain a standard of 50,000 organisms per c.c. and it was felt that if chloroforming or some other purification procedure is adopted all vaccine institutes in India can have purer vaccine without materially increasing the usual storage period. It was, however, felt that all the vaccine institutes may not be able to adopt such special purification measures immediately. It was, therefore, considered desirable to retain the current standard of 20,000 organisms per c. c. for the present and to recommend to the Drugs Technical Advisory Committee to investigate the possibility of improving this standard.

3. The sub-committee also felt it necessary to test for Clostridium tetani and streptococcus haemolyticus in vaccine lymph both at the initial and final stages of vaccine manufacture and not, as prescribed in the Rules, at the final stages only when the plate cound test reveals adequate reduction in the number of extraneous organisms. Testing at the initial stages is also necessary to eliminate the contamination by such dangerous organisms by prompt and total rejection of such contaminated samples. It is hoped that the Drugs Technical Advisory Committee will take necessary action in the matter.

4. The sub-committee considered that the tests officially prescribed are not sufficient to ensure safety of the product unless a safety test on animals is made obligatory. This test is officially prescribed in England and the Vaccine Institute in U.P. has been performing this test on every sample for the last 15 years. It should, therefore, be prescribed and made obligatory. Both guineapig and mouse should be used in performing this pathological test.

5. The sub-committee strongly felt that the entire responsibility of production, storage, testing and issue of safe, potent and reasonably pure vaccine lymph rests upon the bacteriologist or the officer incharge of the Institute. Working within the scope of the prescribed rules and the standards he should have sufficient latitude to improve upon testing methods on approved scientific lines without introducing any factor which may adversely affect the accuracy of the prescribed tests. Rigid uniformity in the testing procedure need not be enforced but specific recommendations on essential points safeguarding the highest possible quality of vaccine lymph must be laid down for the guidance of the bacteriologists and the licensing authorities.

COPY OF LETTER NO. 53/9/48-R. DATED THE 14TH FEBRUARY, 1950, FROM THE SECRETARY, INDIAN RESEARCH FUND ASSOCIATION, NEW DELHI, TO THIS DIRECTORATE.

SUBJECT :—*Provision for vaccine lymph in the Drugs Rules.*

With reference to your letter No. 8-47/49-DAB, dated the 7th January, 1950, on the subject mentioned above, I forward herewith for information a copy of letter No. 573, dated the 28th January, 1950, from Dr. B. S. Yajnik Provincial Hygiene Institute, Lucknow, together with its enclosure. I generally agree with the modifications in the provisions for vaccine lymph suggested by Dr. Yajnik in the Drugs Rules, 1945.

COPY OF D.O. LETTER NO. 573, DATED THE 28TH JANUARY, 1950, FROM DR. B. S. YAJNIK, PROVINCIAL HYGIENE INSTITUTE, LUCKNOW, TO DR. C. G. PANDIT, SECRETARY, I.R.F.A., NEW DELHI.

I thank you for your D. O. letter No. 53/9/48-R, dated the 18th January, 1950. I find it rather difficult to suggest modifications in the Drug Rules 1945, because the prevailing conditions in certain Vaccine Institutes are not known. Vaccine Institutes working in various states may or may not have reasonable facilities to comply with the Rules. It is not desirable to prescribe conditions which may be difficult for certain States to follow immediately.

It is, therefore, undesirable for the present to lower the prescribed temperature of cold storage (from 0°C to —10°C) or to reduce the limit of colony count test (from 20,000 to about 50,000 organisms per c.c.) I have not attempted to modify them in the draft Rules enclosed herewith. Vaccine establishments which are able to maintain a lower storage temperature or are able to prepare purer vaccine should, however, be encouraged to do so.

I have not suggested drastic changes and have adopted the various clauses of the Rules in their present form.

The draft modification deals with the following points:—

1. The Officer Incharge of the Institute has been made responsible for the preparation, storage, testing and issue of the safe potent and reasonably pure lymph.

2. Vaccinal material should be kept as cold as possible from the very time it is collected and not after the reduction in the colony count as provided in the existing Rules.

3. A cold room temperature record should be kept and made available for inspection.

4. Licensing authority has been authorised to prescribe a lower limit of Colony count test for an establishment which may be able to prepare purer vaccine.

5. Tests for various pathogenic organisms should be done both at initial and final stages of the preparation of vaccine. Repeated tests have been suggested and the record of various tests has to be kept.

6. A patnogenicity or toxicity test on guineapig and/or mouse has been prescribed.

It is hoped you will approve the draft amendments and intimate modifications made, if any.

With best wishes.

Draft

(B) PROVISIONS APPLICABLE TO THE PRODUCTION OF VACCINE LYMPH (VACCINIA VACCINE)

1. (No change).

2. *Staff of Establishment.*—(1) Existing 2 is numbered 2(1).

(2) The entire responsibility of production, storage, testing and issue of safe, potent and reasonably pure vaccine lymph rests upon the competent expert.

3. (1) (No change).

(2) (No change).

4. *Precautions to be observed in preparation.*—(1) (No change).

(2) (No change).

(3) (a) (No change).

(b) (No change).

(4) (No change).

(5) (No change).

(6) (No change).

(7) (No change).

(8) (a) From the very time the vaccinal material is collected it shall be kept continuously in an ice bath or in cold storage at a temperature approximating 0°C excepting when it is being subjected to some essential manufacing process like grinding or treatment with glycerol or other partial disinfectants necessary to bring down the number of micro-organisms to the prescribed limit.

(b) Existing 4(8) becomes 4(8)(b).

(c) A four-hourly record of daily temperature of the cold room during day time shall be maintained for inspection.

5. (a) (No change).

(b) (No. change).

6. (1) (No change).

(2) (No change).

7. *Tests for purity and Safety.*—(a) Existing 7(1) is numbered 7(1) (a).

(b) If any establishment is normally able to maintain the number of micro-organisms at a much lower figure than the limit prescribed above all reasonable attempts should be made to see that the same low limit is normally maintained.

Such lower limits may be prescribed by the licensing authority that particular establishment where it is normally practicable.

(2)(a) Tests for the detection of B. anthracis, Cl. Tetani Streptococcus haemolyticus, B. coli or any other pathogen which may prove harmful if introduced into the body by the process of vaccination shall be performed in a manner approved by the licensing authority and a record kept for inspection.

(b) If B. anthracis, Cl. tetani or Streptococcus haemolyticus is found to be present in the vaccine lymph at any stage of its preparation, either before or after the prescribed reduction in the number of living micro-organisms has been effected, the batch of lymph shall be rejected forthwith. But if B. coli or any other pathogen is found which may prove harmful if introduced into the body by the process of vaccination, the lymph must be kept in cold storage till an examination of at least 10 milligrams or 0·01 c. c. of the lymph fails to reveal its presence.

(c) The test for the detection of various harmful organisms in vaccine lymph shall be performed both at the initial and final stage of its preparation irrespective of the number of micro-organisms present therein are more or less than the prescribed limit.

(3) When the prescribed reduction in the number of living micro-organisms has been effected, the batch of vaccine lymph may be issued if—

(a) Tests carried out in a manner approved by the licensing authority on a sample not less than 100 milligrams or 0·01 c. c. have failed to reveal the presence of B. anthracis.

(b) Existing 7(3)(a) becomes 7(3)(b).

(c) Existing 7(3)(b) becomes 7(3)(c).

(d) Tests carried out in a manner approved by the licensing authority on a sample in which not less than 5 c. c. of the lymph is injected under the skin or peritoneal cavity of a healthy guineaping and or 0·5 c. c. under the skin of a healthy mouse fails to produce serious symptoms or death of the animal.

8. *Tests for potency.*—(1) (No change).

(2) (No change).

(3) (No change).

MINUTES OF THE ELEVENTH MEETING OF THE DRUGS TECHNICAL ADVISORY BOARD HELD IN THE OFFICE OF THE DIRECTOR GENERAL OF HEALTH SERVICES, NEW DELHI ON THE 8TH AND 9TH MAY, 1950

Present :

1. Dr. B. N. GHOSH, Carmichael Medical College, Calcutta.
2. Dr. A. ACHARYA, Naya Sarak, Cuttack (Orissa).
3. Dr. U. P. BASU, Director, Bengal Immunity Research Institute, Calcutta.
4. Shri T. S. T. CHARI, Chief Chemist, Central Revenue Control Laboratory, New Delhi.
5. Dr. K. A. HAMEID, c/o. Messrs. Cipla Ltd., Bombay.
6. Dr. B. MUKERJI, Director, Central Drugs Laboratory, 110, Chittaranjan Avenue, Calcutta.
7. Dr. A. K. SEN, Scientific Director, Indian Health Institute and Laboratories Ltd., 45, Ballygunge Place, Calcutta.
8. Shri S. P. SEN, c/o. Messrs. Bengal Chemical & Pharmaceutical Works Ltd., Calcutta.
9. Shri K. V. SUNDARAM AYYAR, 3, Jagadiswara Street, Thiagarayangar, Madras-17.
10. Mr. P. M. NABAR, Drugs Controller, India, Directorate General of Health Services, New Delhi. (*Secretary.*)

1. Intimations had been received from Drs. B. N. Prasad, B. B. Dikshit and K. S. Grewal regretting their inability to attend the meeting.

2. The Secretary announced that the *ex-officio* Chairman could not be present owing to his pre-occupation with the W. H. O. meeting. In the absence of the ex-officio Chairman, Dr. B. N. Ghosh was elected to the Chair.

Item I of the agenda—Confirmation of the minutes of the tenth meeting

3. The comments already received (Appendix I) on the minutes of the tenth meeting and those indicated by Dr. A. K. Sen were taken into consideration and the minutes were confirmed, subject to the following amendments :—

Paragraph 2 *of the minutes*—

(a) *Substitute* the word "moved" by "submitted".

(b) *After* the word, "constitutional", *add* the words "since the bye-laws provided for the election of a Chairman from amongst the members present in the absence of the *ex-officio* Chairman".

(c) *Delete* the second and the third sentences. *Substitute* in their place the sentence :

"Dr. Sen's submission was appreciated by the Chairman".

Paragraph 4(*a*) *of the minutes*—

At the end, *add* the words "both for imported as well as indigenous T. A. B. vaccine".

Paragraph 5(1) *of the minutes*—

At the end, *add* "It, however, considered that the qualifications was acceptable for an Inspector under the Drugs Act".

Paragraph 5(4) *of the minutes*—

Add the following as a new para :—

"Incidentally, the question arose whether Government Institutions manufacturing drugs, Sera and Vaccines have taken out manufacturing licences under the Drugs Act. The Chairman asked the Secretary to submit a note whether the C. R. I. Kasauli, the Haffkine Institute, Bombay, and the King Institute, Guindy, and similar institutions had taken out manufacturing licences. Col : Ahuja stated that his institution had not taken out a manufacturing licence".

4. Following the confirmation of the minutes, Dr. Sen stated that an amendment to the provisions relating to T.A.B. Vaccine in Schedule F to the Drugs Rules specifying the life-period of the vaccine and the need for labelling the date of expiry of potency of the vaccine should be issued. The Secretary stated that necessary action would be taken in due course.

5. Dr. Sen desired that a "life period" for Cholera Vaccine also should be fixed. It was agreed that the Secretary should supply the members with the data for the purpose and that relevant recommendations, if any, made by the I. R. F. A. in this connection should be included in the data.

6. Mr. S. P. Sen pointed out that the methods of analysis followed by Government Analysts in the States varied, with the result that in certain cases, drugs passed by one State Government Analyst had been rejected by another. He suggested that the Director, Central Drugs Laboratory, should confer with the Analysts from the State Governments and the Analysts from the trade, Universities and Research Institutions and arrive at uniform methods in the analysis and assay of drugs. The Board passed the following resolution :—

"The Drugs Technical Advisory Board recommends to the Government of India that steps should be taken to convene periodical meetings of the State Government Analysis and the Director of the Central Drugs Laboratory and also of experts from the trade, Universities and Research Institutions in order to ensure that the methods and procedures followed in standardisation of drugs and in the issue of reports thereon are uniform in all States".

Item II of the agenda—Consideration of questions arising out of the Discussion at the last meeting

7. (a) The Board considered letter No. F. 1-12/48-D, dated 11th February 1949 from the Government of India (Enclosure F to the agenda of the tenth meeting) regarding the amendment of Rule 65(1) and decided to recommend to Government that the Rule should be altered to read :—

"Any drugs specified in Schedule E or any preparation containing any such drug and any drug supplied on any prescription shall, if compounded or made up on the licencee's premises, be compounded or made up by or under the direct and personal supervision of a qualified person".

At the same time, the Board was of the opinion that unless the terms "prescription", "compounding" and "made-up" were defined, there might be legal complications in enforcing the rule.

(b) The Board also agreed that Rule 65(3) should be amended on the same lines as Rule 65(1).

8. (a) The amendment to the proviso to clause (4) of Rule 65, as proposed by the Government of India, Ministry of Health, in their letter No. F. 1-15/49-D, dated the 19th January, 1950 (Encl. Q to the agenda of the tenth meeting), was agreed to by the Board who, however, suggested that a comma should be added after the words "registered medical practitioner" in the proviso.

(b) The Board also considered that, with a view to assisting wholesalers in complying with the above new position, the State Government Authorities should be asked to publish a list of licence holders for the sale of drugs.

9. Letter dated the 6th February, 1950 from Dr. K. A. Hamied (Appendix II to the minutes of the tenth meeting) was considered by the Board.

(a) In regard to "Pennant" labels, the Board was of the opinion that all the details required by Rule 109 need not be indicated on the labels of items under category 12 of Schedule C and that such elaborate details were necessary only in the case of those Schedule C items which were governed by the provisions of the U.K. Therapeutic Substances Act. It was decided that the lebelling requirements of drugs falling under "Any other preparation in a form to be administered parenterally" should be reviewed with a view to excluding them from giving all the details on the labels of the ampoules.

(b) As regards Rule 109(1), the Board considered that its provisions were not impracticable, except in a few stray cases where there were long proprietary names. The composition of Schedule C, items should not be confused with the proper names. In any case, the Board desired that the possibility of excluding Schedule C-12 items from the provisions of Rule 109 (1)(a) should be examined.

(c) *Schedule 'E'*.—It was decided that the amendments to Schedule E which were proposed by Dr. Hamied should be referred to the Poisons Sub-Committee of the Drugs Technical Advisory Board and that he should be invited for the meeting of the Sub-Committee at which the amendments would be discussed.

As regards Para-amino-benzoic acid, the Secretary was asked to ascertain from the Poisons Board U. K. and the U. S. A. Authorities whether that drug was classified by them as a "poison".

(d) *Unsold stocks on* 31*st December,* 1949.—Dr. Hamied was informed that the Government of India had extended the date of disopsal for such drugs up to 30th June, 1950.

(e) Regarding the last para of Dr. Hamied's letter, the Board did not consider it necessary to alter the existing provisions, as the names of poisons and the quantities in which they were present in patent and proprietary medicines which were registered with the Central Drugs Laboratory must be disclosed with a view to assisting the medical practitioners in deciding their dosage.

Item III of the agenda—Consideration of items Nos. IV & V of the agenda of the tenth meeting

(i) Letter No. P&P/6, dated 1st April, 1949 from the Director, Central Drugs Laboratory, Calcutta (Encl. S. to the agenda of the tenth meeting).

10. (a) Dr. B. Mukerji, Director, Central Drugs Laboratory, stated that as more than a year had elapsed since he wrote this letter, he wished to withdraw it.

(b) Mr. S. P. Sen was of the opinion that no relaxation of the provisions of Rule 96(3) in regard to wooden and metal containers ought to have been allowed. It was suggested that he should refer in writing any points which he had in support of his view.

(ii) Consideration of the Therapeutic Substances Amendment Regulations, 1949 (No. 1846) relating to Streptomycin (Encl. : T. to the agenda of the tenth meeting).

11. The draft regulations, as circulated, were accepted by the Board.

(iii) Letter No. 8/27/49-D, dated the 29th October, 1949 from the Secretary, Drugs Technical Advisory Board, to all the members of the Board (Encl.: U to the agenda of the tenth meeting).

12. Mr. Nabar mentioned that it was necessary to encourage the manufacture of Magnesium Sulphate from marine sources, as that would help in conserving valuable Sulphuric Acid for other industrial use. A higher chloride content should not, in his opinion, be harmful to the human system as Magnesium Chloride was also prescribed for the same therapeutic indication as Magnesium Sulphate. The Board decided that if Messrs. Tatas Ltd. desired to secure any exemption from the standards prescribed under the Drugs Act, they should approach the Board through the State Government. Also the question of laying down standards for Magnesium Sulphate from marine sources should be decided by the Indian Pharmacopoeia Committee.

(iv) Letter dated 14th September, 1949 from Messrs. Jagat Singh's Son & Bros. Bombay (Encl.: V to the agenda of tenth meeting).

13. It was considered that the batch number could be marked in any way so long as it was indelible as required by the Rules and so long as the Inspectors etc., and the public were able to follow the indication. The Board felt that it was not competent to interpret Drugs Rules.

(v) Letter No. D. G. H/05/49, dated the 4th May, 1949 from Dr. U. P. Basu, (Encl.: W to the agenda of the tenth meeting) and subsequent letter No. G/046/50, dated 22nd April, 1950 (Appendix II).

14. The suggestions to improve the regulations relating to Bacteriophages were considered. The Board appointed the following Sub-Committee to consider the suggestions and to report on them:—

(1) Dr. A. K. Sen.

(2) Dr. U. P. Basu.

(3) Dr. S. P. Sen.

(4) Dr. B. Mukerji (Convener).

The Sub-Committee was empowered to consult other experts in the field, if necessary.

(vi) Question whether Strophanthus seeds the preparations of Strophanthin not in form to be administered parenterally should be included in Schedule C(1).

(15) The Board recommended that the entry relating to Digitalis against item (1) of Schedule C(1) should be altered so as to cover Strophanthus seeds and preparations of Strophanthin and other Cardiovascular drugs.

(vii) Question whether Rule 124(3) should be amended so as to prevent the import of unstandardised preparations, such as soft extracts of Hyoscymus and Nux Vomica etc., mentioned in the earlier editions of the Pharmacopoeias.

16. The Board was of the opinion that the Rule did not permit of the import of unstandardised preparations included in the B. P. 1885 and 1914.

(viii) Question whether Rule 122 should be amended so as to make it incumbent on the manufacturers to label items like Adrenaline, Ergot and Liver Extracts etc., not in a form to be administered parenterally with the date of manufacture and date of expiry of potency.

17. It was considered that reliable data worked out in this country on the *life-periods* of Adrenaline, Ergot etc., coming under Schdule C(1) was not known. The Board, therefore, considered it inadvisable to make a provision that the dates of expiry of potency should be indicated on the labels of these preparations.

(ix) Question whether item 10 of Schedule C should be amplified to include all synthetic substances having the same physiological action as Adrenaline.

18. The Board was of the opinion that the provisions relating to Adrenaline under category 10 of Schedule C were applicable to Adrenaline of synthetic and natural origin.

(x) Question whether preparations containing Vitamins, Liver Extract & Hormones in any form not to be administered parenterally should be labelled "Not to be injected" as required by the provisions of Section D, E and F of Part XII of Schedule F to the Drugs Rules.

19. (a) Dr. Sen said that as oils, semi-solids and emulsions were used for parenteral administration, it was necessary to provide that sufficient indication was given on the labels to distinguish products meant for parenteral administration from those meant for oral and other use.

(b) The example of Colloidal Calcium with Vitamin D, which was used for the dual purpose of oral and parenteral administration, was quoted by Dr. Basu who stated how necessary it was, in that case, to lebel the oral preparation "Not to be injected" so that it could not, by mistake, be used for parenteral administration.

(c) As against the points of view mentioned above, it was contended that such stray cases should not be considered as providing sufficient justification for the continuance of the labelling provision. It was pointed out that, as a result of pure Vitamins in bulk packing being labelled "Not to be injected" there had been instances where manufacturing establishments had refused to

buy them on the ground that they were unfit for ampouling purposes. Dr. Hamied stated that it would appear ridiculous if solid preparations containing vitamins such as calcium-granules with Vitamins, Malt Extract with vitamins, Hormone ointments etc., were labelled "Not to be injected".

(d) It was decided by a majority of votes that the labelling provision under Sections D, E and F of Part XII of Schedule F to the Drugs Rules requiring Vitamin, Hormone and Liver Extract preparations not meant for parenteral administration to be labelled "Not to be injected" should be deleted. Drs. A. K. Sen, Acharya, U. P. Basu and Mr. Sundaram Ayyar voted against the deletion of the provision, while Drs. Hamied, Mukerji and Messrs. S. P. Sen, Chari and Nabar voted for its deletion.

Item V of the Agenda of the tenth meeting—Consideration of the minutes of the two meetings of the Poisons' Sub-Committee of the D. T. A. B. (Encls. X and Y to the agenda of the tenth meeting.

20. The Board noted that the minutes of the Poisons Sub-Committee, were not confirmed by the members and decided to refer them back for regularisation.

Item V of the Agenda of the tenth meeting—Consideration of the following communications received from the Government of India

(1) Letter No. F. 11-14/50-DS, dated the 9th March, 1950. (Encl.: A to the agenda) regarding the question whether injectible preparations of Ayurvedic and Unani Systems of medicine should not be controlled under the provision of the Drugs Act:

21. The Board desired that the Secretary should obtain concrete instances and details from the Therapeutic Trials Sub-Committee of the I. R. F. A. before the question could be taken up for discussion.

(2) Letter No. F. 1-20/49-DS, dated the 10th February, 1950 (Encl.: B to the agenda) regarding the amendment of Rule 65(5) of the Drugs Rules, 1945 in connection with maintenance of records of purchases and sale by way of wholesale dealing of Schedule C drugs:

22. The amendment proposed by the Government was agreed to.

(3) Letter No. F. 10-21/49-DS, dated the 13th March, 1950 (Encl.: C to the agenda) regarding amendment of the Drugs Rules in respect of the sale of drugs by itinerant vendors, grocers, pan-supari shops, etc., etc.

23. (a) The facts mentioned in the Government of Bombay's letter were taken into account before the Board arrived at a decision in the matter at the last meeting.

(b) The Board again considered letter No. F. 10-21/49-DS, dated the 18th January, 1950 from the Ministry of Health, Government of India, to the Secretary, Drugs Technical Advisory Board, and decided to recommend the addition of words "and not those drugs which require cold storage under the Rules" to para. 3 of the Form 20-A, as well as to para. 4 of Form 21-A, after the words "under the Drugs Rules".

Item V of the agenda—Consideration of the following

(1) Letter dated the 27th December 1949 from Shri K. V. Sundaram Ayyar, Madras (Enclosure: D to the agenda).

24. The Board was of the opinion that the subject matter of the letter would more appropriately fall within the scope of the functions of the Drugs Consultative Committee and that the Secretary should forward the letter for opinon and advice to the Drugs Consultative Committee.

(2) Letter No. 217 dated the 6th February, 1950 from the Indian Chemical Manufacturers' Association, Lucknow (Encl.: E to the agenda) regarding the addition of harmless colouring matter in B. P. tinctures and spirituous preparations.

25. Mr. Sundaram Ayyar stated that, in his opinion, Caramel was *not* a non-interfering or inert substance as was claimed by a section of the manufacturers of drugs. He desired that a list of harmless colours should be compiled by the Board and their addition to Pharmacopoeial preparations defined and stated that he was against the addition of any colouring matter to any Pharmacopoeial preparation if the respective Pharmacopoeia did not specifically allow its addition.

Dr. Basu saw no reason why there should be any objection to the addition of Caramel to Pharmacopoeial preparations when the addition of inert substances such as stabilisers etc., to injectibles was permitted.

Mr. S. P. Sen stated that Caramel was added only to give a uniform colour to such of the Pharmacopoeial preparations as were prepared from crude drugs and that if its use was prohibited, the colour of each batch of the product would vary thereby creating a sense of insecurity in the minds of medical practitioners and others. Uniformity of colour was difficult to achieve for all the batches, despite every care in the selection of the crude drugs.

Dr. Hamied agreed with Mr. Sen and suggested that the use of Caramel should be permitted.

Dr. Mukerji said that an over-all permission for the use of harmless food colours in general was undesirable. The addition of colouring matter should be allowed in a specific proportion only after careful examination. In his opinion, the use of Caramel should be allowed.

Dr. A. K. Sen was of the opinion that the Act and the Rules did not prohibit the use of harmless and inert colouring material. What the Act prohibited was only the colouring, coating, powdering or polishing of Pharmacopoeial preparations in such a way as to conceal any damage or to make in the substandard quality.

Mr. Nabar mentioned that if the Drugs Act and Rules allowed the use of colouring materials such as Caramel, there was a danger that any harmless colouring material might be added in any quantity. Such a contingency should not be allowed to develop.

The Chairman expressed doubts whether all the manufacturers would use the same quality of Caramel and in the same proportion unless there was statutory control over the addition of such colouring matter.

The Board finally decided that legal opinion should be obtained whether the Drugs Act and Rules allowed the addition of harmless and inert colouring matter to Pharmacopoeial preparations, although their addition may not be specifically provided for in the Pharmacopoeias.

(3) Letter dated the 10th February, 1950 from Dr. Jivraj N. Mehta, Bombay, regarding the need for relaxing the provisions for 'qualified person' in the Drugs Rules (Encl.: F to the agenda).

26. The Board was of the opinion that Dr. J. N. Mehta had written a demi-official letter on a matter which pertained to another Ministry in the Bombay Government. If the State Government desired to have any such

clarification, they ought to have written direct to the Board. It was suggested by one of the members that the letter should be forwarded to the Government of Bombay who should be asked to refer the case to the D. T. A. B., if they considered it necessary.

It was, however, decided that relevant extracts from the letter should be forwarded to the Pharmacy Council of India for its opinion.

(4) Consideration of amendments to the provisions relating to vaccine Lymph in the Drugs Rules as suggested by the I.R.F.A. (Encl.: G to the agenda):

27. A copy of letter No. G/053/50, dated the 2nd May, 1950 from Dr. U. P. Basu (Appendix III), was also put up before the Board for consideration.

28. It was considered that the question ought to have been referred to the Board through the Government of India, Ministry of Health. The Secretary was asked to explain the appropriate procedure to the I. R. F. A.

Item VI of the agenda—Consideration of insertion of a new Rule 30A

29. Mr. Nabar explained the need for the proposed new rule. It was decided by the Board to recommend to the Government the addition of a new rule 30A, between 30 to 31 of the Drugs Rules, 1945, reading as follows :—

"30-A. Prohibition of Import of certain drugs.—No drug, the manufacture, sale or distribution of which is restricted or prohibited in the country of origin, shall be imported under the same name or under any other name except for the purpose of examination, test or analysis."

Item VII of the agenda—Any other business

30. The Board desired that the Central Government should impress on the State Governments the need for the uniformity in the numbering of Rules and Schedules in the Drugs Rules issued by different State Governments in order that there should be no confusion in Inter-State correspondence.

31. The Secretary was requested to send to the members of the Board copies of the Drugs Rules, 1950, when the revised edition was printed.

32. The following resolution was passed by the Board:—

"In view of the importance that is being attached to the subject of Pharmacognosy, the D.T.A.B. recommends to the Government of India that a full-fledged section of Pharmacognosy should be established in the Central Drugs Laboratory with the same scale of staff and emoluments as has been sanctioned for the four sections that are working at present in the Central Drugs Laboratory".

Consideration of the following communication from the Government of India, Ministry of Health :—

Letter No. 1-14/49-D, dated the 24th April, 1950 regarding exclusion of preparations of Sulphonamides from the purview of Schedule H of the Drugs Rules (Appendix IV).

33. The suggestion made by the South India Chemists & Druggists Association was not agreed to by the Board.

Endorsement No. 1-6/50-DS, dated the 25th April, 1950 regarding introduction of provisions in Schedule F in respect of B. C. G. Vaccine (Appendix V):

34. It was decided that the matter should be circulated to the members so that it could be discussed at the next meeting.

Letter No. F. 1-22/49-DS, dated the 14th April, 1950 proposing the withdrawal of the exemption allowed in the labelling provisions of drugs sold for export to places outside India :

35. Dr. Hamied read out his note on the subject (Appendix VI).

The Board did not agree with the amendments proposed by the Government of India, as in its opinion, such a provision would hit hard the drug exporting firms in India who have to comply with the labelling provisions of the country to which the drugs are exported.

It was, however, considered that manufacturers of drugs for export should be made to take out a licence for the purpose, as otherwise drugs not labelled in accordance with the labelling provisions might be freely manufactured by unscrupulous firms on the plea that they are meant for export. In issuing such licences, the applicants must be made to produce documentary evidence to prove that either they have been exporting drugs in the past or that they have received orders for export.

Letter No. 29/50, dated the 27th February, 1950 from the All India Chemists & Druggists Federation, New Delhi, (Appendix VII) suggesting that the sole-agency clause for the import of Schedule C drugs should be done away with.

36. The consideration of this letter was postponed to the next meeting.

37. The draft notification proposed to be issued by Government (Appendix VIII) relating to the extension of the provisions of the Drugs Rules to certain States in the country was agreed to by the Board.

38. Letter dated 31st May, 1949 from Messrs. H. J. Foster & Co. Ltd., Bombay (Appendix IX) regarding "Adrenaline Hydrochloride B. P." was considered and it was decided by the Board that the provisions relating to that item under Schedule C should be deleted.

39. Memo. No. Misc. 1/49/927, dated the 7th December, 1949 from the A. D. C., India, Bombay (Appendix X) regarding amendment to Rule 106 of the Drugs Rules was considered by the Board. Rule 106 was framed under the powers vested in Section 10(a) and 19(iv) of the Drugs Act. The Board considered that the words "to have any such other effect as may be prescribed" occurring in these two sections have sufficient powers to control those labelling statements which claimed to *prevent* any of the diseases mentioned in Schedule J.

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

APPENDIX I

Comments received from members of the Drugs Technical Advisory Board on the Draft minutes of the tenth meeting of the Board

Dr. K. A. Hamied :

"Re: Page 3 of the Minutes, last paragraph, I wish to draw your attention to the fact that I pointed out that when the Hakims and Vaids, who were registered under the Medical Practitioners Act, are allowed to use Sulpha drugs and other medicines falling under Schedule H, why the members of the All India Private Medical Practitioners should be debarred from doing so. They have more experience in the use of Allopathic medicines than the Hakims and Vaids. As this matter is going to be considered by the State and Central Governments the addition of these remarks in the Minutes would be helpful to the Medical Practitioners. The rest of the minutes are correct."

Dr. Khem Shing Grewal :

"Reference your No. 9-5/50-DAB of 25th March, 1950, I agree to the minutes subject to the following remarks. On page 4 item III of the agenda (1) second line after suggestion there should be—to the appointment of such persons as public analyst, they can however be appointed as inspectors.

The same page Rule 124(1) line 4 word proposed be deleted and after the word Pharmacopoeia under compilation be added."

Shri S. P. Sen :

"Item VI of the Agenda :

(a) While decision of the potency period of the T. A. B. Vaccine was taken, it was suggested (by Mr. Sen) that similar time limit should be insisted upon for the same item of the foreign manufacturers also and the decision was taken that 'the T. A. B. Vaccine of the foreign manufacturers should indicate the time limit as directed by the D. T. A. B. Products not containing this time limit coming from abroad shall not be allowed to be cleared at the customs'.

I think this should be incorporated in the minutes and I believe that it was omitted through oversight.

(b) As a corollary to the decision of time limit as arrived at in the case of T. A. B. Vaccine the question naturally arises as to what will be the position in regard to the Anti-Cholera Vaccine and other vaccines. I think it is necessary that the question of the life period of these products also are decided at an early date. I would, therefore, like to suggest that this point be discussed at the next D. T. A. B. meeting and a proper decision taken.

Item VI of the Agenda:

I think that along with the decision of the uniformity in the control of the Drugs Rules taken by the D. T. A. B., a uniformity in the control on Drugs analysis in different laboratories should also be found out. I would, therefore, like to suggest that 'a procedure be evolved by the Co-ordinating body that similar methods and processes of assay and analysis of drugs should be adopted by all the Provincial Laboratories as also the Central Drugs Laboratory'. This I can say from my personal experience that the same drug has been found to yield different results at different laboratories.

Sometimes the difference verges on the border of absurdity. Please allow me to cite an example. An Extract Ergot Liqd. was found to be 3 times stronger than B. P. and in another laboratory it was found to be weaker. Tablet Ephedrine Hydrochloride was declared to contain excessive filling materials and therefore not B. P. B. P., however, does not indicate about the quantity of filling materials. Such reports are prejudicial to the interest of the Industry and the D. T. A. B. may evolve a procedure to remedy this defect."

Dr. U. P. Basu :

"I have gone through the draft minutes of the meeting of the D. T. A. B. held on the 20th and 21st February, 1950. I find no reference to the discussion that took place on the question of taking manufacturers licence by Government Manufacturing Organisations. This was most probably discussed under (4) of Item III of the Agenda. The Chairman specifically asked Col. Ahuja to enlighten on the issue; when Col. Ahuja answered in the negative as they have not taken manufacturers licence according to the Drugs Rules.

Secondly I feel that the decision taken on the time limit for life period of typhoid and paratyphoid vaccines (*vide* page 2 of the minutes) is not proper as it stands against our existing Drugs Rules—clause 3 of Part XII."

APPENDIX II

Copy of a letter No. G/046/50, dated the 22nd April, 1950 from Dr. U. P. Basu, D.Sc., F.N.I, Director, Bengal Immunity Research Institute, 39, Lower Circular Road, Calcutta 16, to the Secretary, Drugs Technical Advisory Board, New Delhi

SUBJECT :—*Provision applicable to the Production of Bacteriophages.*

I have gone through the various questions raised and different suggestions forwarded by the Director, King Institute, Guindy, Madras and by the Officer-in-Charge, Provincial Public Health Laboratory, Patna.

It is difficult to fix up any date of potency at present as no statistical data are available. Various clauses may be retained as already suggested. But with regard to the clause "Tests" the following specifications be prescribed :

(i) *Sterility*.—Bacteriophage shall be subjected to the same test for sterility as prescribed in those rules for bacterial vaccines; and the sealed bacteriophage ampoules shall be incubated at 37°C for 48 hours when no ampoule should show any turbidity.

(ii) *Potency*.—Bacteriophage shall be subjected to a potency test against the homologous organisms by the serial dilution method and each shall contain on any day up to its period of potency viable phage corpuscles to bring about a complete lysis of an actively growing young cultures containing not less than 50 millions of organisms per c. c. in a dilution not less than 1-100,000 in a total volume not more than 10 c. c. The first tube should show complete lysis within 24 hours.

For finding out the Life Period a special sub-committee consisting of the Director, Central Drugs Laboratory; Director, King Institute; Dr. A. K. Sen; the Officer-in-Charge of Public Health Laboratory, Patna; and two experts from Manufacturing concerns, be appointed to consider the problem from various angles.

The letter be circulated to the members of the Drugs Technical Advisory Board with the permission of the Chairman.

APPENDIX III

Copy of letter No. G/053/50, dated the 2nd May, 1950, from Dr. U. P. Basu, D.Sc. F.N.I., Director, Bengal Immunity Research Institute, 39, Lower Circular Road, Calcutta 16, to the Secretary, Drugs Technical Advisory Board, New Delhi

SUBJECT :—*Provision for Vaccine Lymph in the Drugs Rules.*

With reference to the Agenda of the 11th Meeting of the D. T. A. B. [Item No. V (4)], I referred the matter to the Health Officer, Corporation of Calcutta. The Health Officer has forwarded certain observations from the Superintendent, Vaccine Institute, Corporation of Calcutta. This I am forwarding to you and be placed for consideration by the Members of the D. T. A. B. at the next meeting.

Observations

REF. :—*Total bacterial count of the lymph (para 2 of Encl.: G)—Agenda Item No. V(4)* :

The standard of 20,000 viable organisms per c. c. prescribed for the plate count is capable of further improvement. Recently, this laboratory has been able to reduce the number of viable organisms to negligible figures by treating with penicillin (300 units per c. c.) without in any way affecting the potency of the lymph. With the limited experience at our disposal, we believe this to be one of the best methods of purifying lymph.

REF. :—*Testing for the presence of Cl. tetanis and strepto haemolyticus (para 3 of Encl. G)* :

This should be done both at the initial and final stages of vaccine manufacture, the test at the initial stage being necessary for the prompt and total rejection of contaminated samples.

REF. :—*Inoculation of guinea pigs and mice (para 4, Encl. G)* :

Inoculation of guinea pigs and mice with vaccine lymph to test the pathogonicity and toxicity of the lymph should be made obligatory, though this will involve a large increase in expenditure as the cost of laboratory animals is very high.

A. G. GANGULY,

(Offg.) *Superintendent, Vaccine Institute.*

APPENDIX IV

Copy of a letter No. 1-14/49-D, dated the 24th April, 1950 from the Government of India, Ministry of Health, New Delhi, to the Secretary, Drugs Technical Advisory Board, New Delhi.

SUBJECT :—*Drugs Rules, 1945— Exclusion of preparation of sulphonamides from the purview of Schedule H—Amendment of.*

I am directed to say that Messrs. Smith Stanistreet and Co. Ltd., Calcutta made a representation to the Drugs Technical Advisory Board to the effect that ointments and surgical dressings containing sulphonamides should be excluded from the purview of Schedule H to the Drugs Rules. The Board considered the matter in its eighth meeting held on the 28th and 21st November, 1948, and agreed to the firm's proposal *vide* para 5(2) of the minutes of the meeting. A preliminary notification containing a draft amendment to Schedule H to the Drugs Rules as published for objections and suggestions from the public by the Central and Part A State Governments. The South India Chemists and Druggists Association have made certain comments on this amendment *vide* their letter No. G/127-49, dated the 18th October, 1949 (copy attached). I am to request that the matter may be placed for consideration before the Board at its next meeting and their views communicated to this Ministry.

Copy of letter No. G/127/49, dated the 18th October, 1949, from the South India Chemists & Druggists Association, to the Ministry of Health, Government of India, New Delhi.

SUBJECT :—*Draft Amendments—Suggestions.*

Reference No. F. 1-14/49-D, dated the 2nd July, 1949 published in the Gazette of India, Part I, Section I, dated the 30th July, 1949, draft amendment to Schedule H of Drug Rules 45.

With reference to the above proposed draft amendment to Schedule H of Drugs Rules 45, I wish to state that 'para-aminobenzene-sulphanilamides' either original drugs or their salts or preparations when used externally are not at all harmful, and no restrictions on their sale may be found necessary. Hence, I may be permitted to suggest that the draft amendment may please be worded as:—

"But excluding original drugs or their salts or preparations and dressings containing these when intended for external use".

Thanking You.

MINISTRY OF HEALTH

NOTIFICATION

New Delhi, the 2nd July, 1949.

No. F. 1-14/49-D.—The following draft of a further amendment 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 section, for the information of all persons likely to be affected thereby and notice is given hereby that the draft will be taken into consideration on or after the 30th October, 1949. Any objection or suggestion 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 Amendment

In Schedule H to the said Rules, to the entry beginning with the word "Para-aminobenzene-sulphonamide" and ending with the words "their salts" the following shall be added, namely :—

"But excluding preparations and dressings containing these for external use."

J. N. SAKSENA,

Under Secretary.

APPENDIX V

No. 1-6/50-DS.

Copy with enclosure forwarded to the Secretary, Drugs Technical Advisory Board (C/o Directorate General of Health Services) with the request that the matter may be placed before the Board at its next metting. The views of the State Government when received will be communicated to you.

J. N. SAKSENA,

Under Secretary.

Copy of letter No. F. 1-6/50-DS, dated 25-4-50 from the Ministry of Health to All Part A State Governments.

SUBJECT :—*Drugs Rules, 1945—Introduction of Provisions in Schedule F in respect of B.C.G. Vaccine.*

I am directed to say that, as the State Government are already aware, B. C. G. Vaccine has been introduced in the country in the treatment of Tuberculosis. With the introduction of the vaccine, it was considered necessary to take steps to control the import into and the manufacture and distribution of B. C. G. Vaccine in the country. Necessary steps have already been taken by the Government of India to prevent the import of the vaccine into India. As regards steps to control the manufacture of the vaccine, I am to say that the proposal is to manufacture the vaccine under Government auspices. Notwithstanding this, it is considered necessary that certain provisions should be introduced in the Drugs Rules, 1945 to ensure that the vaccine manufactured in the country conforms to certain standards. It is proposed to amend the Drugs Rules for this purpose 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 Rules can be taken after the views of the Board are obtained. As the matter is proposed to be placed before the Board at its next meeting to be held in the second week of May, 1950, the State Government are requested to send their reply before that.

J. N. SAKSENA,

Under Secretary.

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 sections 12 and 33 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 ..... 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 Amendment

In Part I of Schedule F to the said Rules after Head (C) and the entries thereunder the following Head and entries shall be inserted namely :—

(CC) PROVISIONS APPLICABLE TO B.C.G. VACCINE

1. Definition and proper name of the vaccine.—B. C. G. Vaccine is a suspension of a living culture of attenuated mycobacterium tuberculosis of bovine type (Bacille Calmettee-Guerin). Its proper name is B.C.G. Vaccine.

2. **Strain of organism to be used.**—The strain to be used in the preparation of B.C.G. vaccine shall be derived from the original strain of Calmette and Guerin.

3. **State of establishment.**—The establishment in which BCG vaccine is prepared must be under the complete direction and control of a competent expert. The staff should be adequate for—

(a) carrying out the operation and tests required during the preparation of the vaccine and in connection with the finished product, and

(b) for the work being carried out in the case of absence of one or more of its members.

All staff members including the persons who clean the building should be in good health and should be free from any infectious disease. They should be medically examined by a competent expert, special attention being paid to the absence of any form of tuberculous infection. The medical examination should be repeated every three months.

All members of the staff should work only on B. C. G. and should not be engaged in laboratory work involving culture or handling of other micro-organisms.

4. **Condition and housing of animals.**—The animals used in connection with the preparation of BCG vaccine shall be housed in clean and hygienic premises. No one except the members of the staff shall have access to the animal house. The animal inoculation and post-mortem examinations necessary for the testing of the BCG strain and batches of vaccine shall be conducted in the animal house which shall be separate from the BCG unit or on a different floor.

5. **The building.**—The preparation of BCG vaccine shall be carried out in a separate and self contained unit used exclusively for BCG work, which shall be housed in a separate building or on a separate floor of a larger building provided that the location is such as to render negligible any risk of contamination with virulent tubercle bacilli or other organisms.

Visitors should not be permitted to enter any of the laboratories concerned in the production of BCG vaccine unless proved free from Tuberculosis infection.

Glassware, utensils and other instruments should never leave the BCG unit. The preparation of all media and other materials and all sterilizations should take place in the BCG unit.

6. **Precautions to be observed in the preparation of BCG vaccine.**—(a) Full precautions shall be taken against bacterial contamination through the agency of air, water, equipment or personnel. All the workers in the unit should wear laboratory gowns.

(b) Workers immediately engaged in the direct preparations of the vaccine should wear clean cap, mask, gown and footwear which shall be kept in a room leading to the entrance of the rooms where the vaccine is handled.

The cleaning and the maintenance of these rooms should be under the direct supervision of a qualified technician.

All the rooms in the unit shall be kept locked when not in use. The incubators should be kept locked. The keys of both the rooms and incubators shall be kept in the custody of the Chief of the Laboratory or his first Assistant.

7. **Records.**—The licensee shall maintain permanent records of :

(i) The origin and date of reception of the seed strain, the date of sub-cultures or the strain and method of sub-cultivation employed.

(ii) The morphological character of the culture at all relevant stages during the manufacture of the vaccine and the method of preparation of each batch of vaccine shall be kept on record.

(iii) The test for sterility, potency, inoccuity and skin sensitizing potency.

8. **The control tests.**—(a) *A sterility test.*—Suitable aerobic and anaerobic methods should be used.

(b) *An inoccuity test.*—At least 5 mg. of BCG bacilli of the prepared vaccine are injected subcutaneously or intraperitoneally into one or more guinea pigs. The animals are sacrificed and examined after six months' observation.

(c) *A test for skin sensitizing potency.*—Five mg. of BCG bacilli of the prepared vaccine are injected subcutaneously or intraperitoneally into one or more guinea pigs. After four weeks the intracutaneous injection of 0·1 cc. containing 100 units tuberculine or its equivalent of P. P. D. should produce an area of enduration and Oedema not less than 5 mm. in diameter.

(d) *A potency test.*—Graded doses of the finished vaccine should be injected intrademally into one or more white guinea pigs. One of these doses should be equal to the human dose. The potency of the vaccine should also be compared with the results obtained in children.

9. **Labelling.**—The label should indicate the batch number and the date of preparation of the vaccine which shall be the date on which the vaccine is passed for issue.

10. **Issue.**—BCG vaccine shall not be avaiable for sale to the public. It shall be issued only to centres established by Govt. or local bodies or organizations approved by Government. The vaccine should be administered only by personnel specially trained in the technique.

The vaccine should be used within 10 days from the date of preparation and should be stored at a suitable temperature till required for issue.

APPENDIX VI

Copy of letter No. F. 1-22/49-DS., dated the 14th April, 1950, from the Under Secretary to the Govt. of India, Ministry of Health, New Delhi to the Secretary, Drugs Technical Advisory Board, New Delhi

SUBJECT :—*Drugs Rules, 1945—Amendment of—withdrawal of the exemption of drugs sold for export to places outside India from the labelling and packing provisions.*

In continuation of this Ministry's letter of even number dated the 18th January, 1950, on the subject mentioned above, I am directed to say that replies have been received from all State Governments agreeing to the proposals containd therein. The Government of Bombay have however agreed to the proposals subject to certain observations. A copy of that Government's letter No. 4121/33/5671-H, dated the 14th February, 1950 is enclosed herewith and may be placed before the Board.

Copy of letter No. 4121/33/56571-H, dated 13th February, 1950, from V. S. Mahajani, Esqr., Deputy Secy. to the Govt. of Bombay, Local Self Govt. and Public Health Department, to the Secy. to the Govt. of India, Ministry of Health, New Delhi

SUBJECT :—*Drugs Rules— Exemption of drugs sold for export to places outside India from Labelling and Packing provisions.*

I am directed to refer to your letter No. F. 1-22/49-DS, dated the 22nd December, 1949, on the subject mentioned above and to state that the proposed deletion of rule 94(1) of the Drugs Rules will make it compulsory on the part of manufacturers in this country to comply with the labelling requirements in the case of drugs to be exported. This may result in the drugs not being allowed to be imported into countries outside India on the grounds that they do not comply with the labelling requirements of the importing countries. It is, however, absolutely essential to see that the reputation of the Indian Pharmaceutical industry in the foreign countries does not suffer and it is necessary to take proper precautions to achieve the object. The Government of Bombay would therefore suggest that the rules should be so modified that :—

(1) for countries which have legislation comparable to the Drugs Act 1940, the quality as well as the labelling and packing should be in accordance with the requirements of such legislation.

(2) for countries where there is no such legislation, the quality and the labelling and packing should be in accordance with the Drugs Act, 1940.

2. The Government of Bombay agrees to the matter being referred to the Drugs Technical Advisory Board subject to the observations made in paragraph 1 above.

Note by Dr. K. A. Hamied on "provisions relating to Labelling and Packing in part IX of the Drugs Act".

This matter was placed in the last meeting of the Drugs Technical Advisory Board held on 20th and 21st February, 1950. The general sense of the meeting was that for export to places outside India exemption from labelling and packing provisions of the Drugs Rules be continued. However

it was suggested that I should prepare a note on this subject to be placed at the next meeting of the D. T. A. B. The question of withdrawing the exemption from labelling and packing rules for drugs exported outside India arose from the letter of the Ministry of Health to the Provincial Governments dated 22nd December, 1949. In this letter it was stated that "the Government of India have received representations stating that this exemption may be misused by the trade which would result in the export of substandard drugs with misleading labels". "In order that the reputation of the Indian Pharmaceutical Industry in foreign countries may not suffer, it is considered that the exemption should be withdrawn".

In this connection I would very much like the Government to disclose to the D. T. A. B. the name of parties who have made such representations, If representations have been made by any foreign countries, the question will assume a different aspect and shall be decided on a reciprocal basis. If representations are made by the Indian Medical Profession, then such representations should be examined from a totally different angle.

It is well-known that Indian made drugs and medicines have very small market outside India. The rules and regulations in every country regarding the import of drugs and medicines are different from country to country. All Pharmaceutical manufacturers whenever they are in a position to export to any outside country have to comply with the regulations regarding import and sale of drugs in those countries. It will therefore be of no use enforcing the provisions of labelling and packing regulations prevalent in India to drugs exported to foreign countries for in such a case the labelling and packing will have to be done according to the Indian Drugs Act and again according to the rules prevalent in foreign countries. Further I wish to point out that the Indian Drugs Act is a copy of the British Drugs Act. In other countries this Act may not be applicable and in some countries the regulations may be more severe. In such an event the enforcement of the provisions of labelling and packing of the Indian Drugs Act will only create more difficulties for the Pharmaceutical Manufacturers and would definitely hamper export trade. To give a concrete example, I wish to point out that rules and regulations of the Health Ministry in Egypt are so stringent that not a single medicine made in India can pass through the customs barrier unless every product is analysed and accepted by the Health Ministry. Only then the import of drugs is permitted. In Turkey the position is still severe. After fighting over a year, Indian medicines are not accepted by the Health Ministry in Turkey as the Health Ministry insists that every product should be in accordance with the rules of their Ministry.

Another point which I would bring to the notice of the Members of the D.T.A.B. is that only a few well-known Indian Pharmaceutical Manufacturers are able to export their medicines on account of the reputation which they have gained in foreign countries. In Pharmaceutical Trade reputation of the Manufacturer as regards standard and quality of their drugs is very important. No manufacturer will ever jeopardise his reputation by exporting substandard drugs with misleading labels as has been alleged in the representation sent to the Government.

In many foreign countries the Drugs Act prevalent does not apply to exports. Uptil recently substandard preparations were coming into India from Continental Manufacturers and Manufacturers in U. K. and U. S. A. Since the enforcement of the Drugs Act in India, all these foreign Manufacturers have now to comply with the Indian Drugs Act and not the Drugs Act of their country. It stands to reason therefore that there should be no

enforcement of the provisions of labelling and packing for drugs and medicines which are exported outside India as this will have to comply with the Drugs Regulations of the respective countries. Withdrawal of the present exemption will definitely hamper the export trade and increase the work of the Manufacturers in complying with the provisions of the Indian Drugs Act and again with the provisions of the rules and regulations of the foreign countries. In my opinion, therefore, the present exemption should continue and I hope that members of the D. T. A. B. would agree with my suggestions.

K. A. HAMIED.

APPENDIX VII

A copy of letter No. 29/50, *dated* 27-2-1950 *from the All India Chemists & Druggists Federation, New Delhi to the Drugs Controller, India, Directorate General of Health Services, New Delhi.*

I have pleasure to hand you herewith a copy of a resolution adopted at the sixth annual General Meeting of the Federation held here on the 24th and 25th instants for your information and necessary action.

"Resolved that the Government of India be requested to omit in Form 9 para (1) of Rule 24 of the Drugs Rules, 1945, the second portion relating to the matter of sole agent as the Rule as it only encourages monopoly business to the detriment of the interests of the trade and the Public and as the Rule even after this omission will be sufficient to serve the purpose of the Drugs Act relating to the quality of Drugs."

Proposed by Mr. J. K. Das.

Seconded by Mr. V. C. Gandhi.

APPENDIX VIII

(*To be published in Part II, Section* 3 *of the Gazette of India*)

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 sections 12 and 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..... . 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 Amendment

In the said Rules, for clause (2) of Rule 1, the following shall be substituted, namely :—'(2) Parts I to IV extended to the Parts A and C States, and the remaining Parts to the Part C States'.

Under Secretary (III)

To

The Publisher,
Gazette of India,
NEW DELHI.

APPENDIX IX

Copy of letter No. Nil, dated the 31*st May,* 1949, *from M/s. H. J. Foster & Co. Ltd., Bombay to the Drugs Controller, India, New Delhi.*

SUBJECT :—*Liq. Adrenaline Hydrochloride B.P.*

According to Schedule F of the Drugs Rules, injections of Adrenaline sold in this country must consist of Liq. Adrenaline Hydrochloride B. P. in the new British Pharmacopoeia 1948, however, the only official injection is Injection of Adrenaline Tartrate, and it seems doubtful from the monograph whether Liq. Adrenaline Hydrochloride is intended for injection at all since no dose is given, neither is the official solution sterile.

We should be glad to have your observations on this.

APPENDIX X

Copy of memorandum No. Misc. 1/49/927, *dated* 7*th December,* 1949, *from the Assistant Drugs Controller, India, Bombay, to the Drugs Controller India, D.G.H.S.*

SUBJECT :—*Rule* 106 *of the Drugs Rules.*

Attention is kindly invited to the Ministry of Health Notification No. F. 1-5/48-D, dated the 7th October, 1949, published in the Gazette of India dated the 15th October, 1949.

It is presumed that the draft amendment derives its authority from section 12(2)(d) and 33(f) of the Drugs Act, 1940. It will be seen that these sections as now worded do not envisage the prevention of any specified disease, the actual words used in the relevant sections being 'cure' or 'mitigate'.

This point is being brought to the notice of the Directorate for any action, if deemed necessary.

MINISTRY OF HEALTH

NOTIFICATION

New Delhi, the 7*th October,* 1949.

No. F. 1-5/48-D.—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 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 15th January, 1950. 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

I. In the said Rules *for* rule 106 the following rule shall be *substituted,* namely :—

"106. Diseases which a drug may not purport to prevent or cure.—No drug may purport or claim to prevent or to cure one or more of the diseases or ailments specified in Schedule J or to procure or assist to procure miscarriage in women."

II. For the heading to Schedule J annexed to the said Rules the following heading shall be *substituted* namely :—

"Diseases and ailments (by whatever name described) which a drug may not purport to prevent or cure."

J. N. SAKSENA,
Under Secretary.

GIPN—S2—1 M. of Health/58 [11th Meeting]—18-11-59—400.