Agenda for the Sixth Meeting of the Drugs Technical Advisory Board to be held in the Office of the Director-General, Indian Medical Service, New Delhi, on the 25th February, 1947.

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1. Confirmation of the minutes of the fifth meeting.

2 Consideration of comments received from the Public on draft amendments to the Drugs Rules,

(a) consequent on the introduction of provisions relating to Penicillin and Bacteriophages; and

(b) relating to the functions of the Central Drugs Laboratory.

3. Consideration of Government of India's suggestion that the Indian Pharmacopoeial List be included as a standard under the Drugs Rules, 1945.

4. Question of amendments to certain Drugs Rules.

5. Preparation of draft rules regulating the control of advertisements relating to medicines.

6. Consideration of changes proposed by Government of India in Forms Nos. 6, 8, 14A, 19, 24 and 27 under Schedule A to the Drugs Rules.

7. Consideration of resolutions to be moved by Mr. M. L. Schroff.

8. Any other business allowed by the Chairman.

6th Meeting of the DTAB

Minutes of the Sixth Meeting of the Drugs Technical Advisory Board held on the 25th and 26th February, 1947, in the Office of the Director-General, Indian Medical Service, New Delhi.

PRESENT.

(1) Lieut.-General R. HAY, C.I.E., K.H.P., I.M.S., Director-General, Indian Medical Service, New Delhi . . . . Chairman.

(2) DR. S. S. AIYAR, PH.D., F.R.I.C., Chief Chemist, Central Revenues, New Delhi.

(3) DR. U. P. BASU, D.SC., F.R.S., Chief Chemist, The Bengal Immunity Co., Ltd., 153, Dharamtolla Street, Calcutta.

(4) DR. B. N. GHOSH, M.B.E., F.R.S., (Edin.), F.R.F.P. & S., Professor of Pharmacology, Carmichael Medical College, Calcutta.

(5) DR. P. C. GUHA, D.SC., F.N.I., Department of Pure and Applied Chemistry, The Indian Institute of Science, Bangalore.

(6) DR. B. MUKERJI, M.D., D.SC., F.N.I., Director, The Central Drugs Laboratory, Calcutta.

(7) Lt.-Col. H. W. MULLIGAN, I.M.S., Director, The Central Research Institute, Kasauli.

(8) MR. M. L. SCHROFF, A.B. Hons. (Cornell), M.S. (MIT.), 7, Lower Rawdon Street, Calcutta.

(9) DR. ANIL KUMAR SEN, M.B., 45, Ballygunge Place, Calcutta.

(10) MR. P. M. NABAR, Chief Advisory Chemist, Office of Director-General, Indian Medical Service, New Delhi . . . . Secretary.

1. The Chairman referred to the death of Dr. S. Rajagopal Naidu, who was a member of the Board. A note of condolence was passed.

2. Apologies for absence had been received from Drs. Vyas, Prasad, Dikshit and Minett.

Item (1) of the Agenda :—**Confirmation of the minutes of fifth meeting :**

3. (*a*) No member who attended the fifth meeting had any remarks to offer on the minutes of that meeting, which were confirmed, subject to the following additions and alterations.

Page 8, para . 30 :—Alter the sentence reading " A further duty of the Sub-Committee would be to investigate....." to " A further duty of the Sub-Committee will be to investigate.....".

Last line of para. 30 :—Add the words " as far as possible " after the word " work".

(*b*) Arising out of the minutes of the fifth meeting, copies of letter No. F. 1-1/47-D, dated the 8th February, 1947, received from the Government of India, Department of Health, with reference to para. 15 of the minutes of the fifth meeting were circulated to the members with the relevant portions of the Sea Customs Act. It was decided that an extract of Section 18 from the Sea Customs Act, which is referred to in Section 11 (1) of the Drugs Act, should also be circulated to the members, and the letter be then considered at the next meeting of the D.T.A.B.

4. The question, whether copies of the minutes of the meetings of the Board were

Dr. A. K. Sen. It was pointed out that, with a view to ensuring co-ordination of correspondence with the Provincial Governments, copies of the minutes had been sent to the Provincial Governments by the Government of India. The Board decided that, when the minutes are printed, printed copies should be sent to the Provincial Governments direct by the Secretary.

Item (2) of the Agenda :—**Consideration of comments received from the public on the draft amendments to the Drugs Rules;**

(*a*) consequent on the introduction of provisions relating to Penicillin and Bacteriophages (Appendix I), and

(*b*) relating to the functions of the Central Drugs Laboratory (Appendix II) :

(*a*) (i) Provisions relating to Penicillin :

5. The chairman explained that the draft provisions for Penicillin already published were based on the Therapeutic Substances Amendment (No. 2) Regulations, 1944 (Statutory Rules and Orders, 1944, No. 922) which have since been superseded by the Therapeutic Substances Amendment Regulations, 1946 (Statutory Rules and Orders, 1946, No. 467)—Appendix III—and that most of the comments received on the published draft provisions could be met by accepting the latest U.K. regulations as the basis for framing the provisions under the Central Drugs Rules.

6. Lt.-Col. Mulligan suggested that, as the B.P. had included several preparations of penicillin, penicillin products for parenteral injection should be included in Schedule C to the Drugs Rules and other preparations of penicillin should be placed in Schedule C (1). He added that penicillin in the form of a solution would not be stable under the climatic conditions in India. These suggestions were agreed to and Col. Mulligan was requested to draft suitable provisions for the Drugs Rules on the basis of the Therapeutic Substances Amendment Regulations, 1946. Subsequently, Col. Mulligan, while placing his draft provisions for penicillin before the board, pointed out that there were some deviations in the draft from the Therapeutic Substances Regulations, 1946. It was decided that the draft provisions drawn up by Col. Mulligan should be sent to the Medical Research Council authorities in the U.K. for any suggestions they may desire to make in the light of the latest experience they would have gained in the manufacture and supply of penicillin and that the draft provisions should be circulated to the members of the Board after receipt of a reply from the U.K. and be considered at a meeting of the D.T.A.B.

(*a*) (ii) Provisions relating to Bacteriophages :

7. The Board considered the suggestions put forward to amend the existing rules regarding bacteriophages. The Board decided that sterility tests for aerobic and anaerobic organisms as at present prescribed were essential for safety and that incubation at 37°C. for one week was not acceptable as a substitute, although there was no objection to the latter procedure as an additional precaution. In view of the Board's decision the question of the addition of a preservative did not arise. The Board recommended that the provisions for bacteriophages as already published should stand unaltered.

(*b*) Provisions relating to the functions of the Central Drugs Laboratory :

8. As regards the comments received from the Indian Chemical Manufacturers' Association on the allocation of the functions of the Central Drugs Laboratory, the Board wished to emphasise that it had accepted the rule as a provisional measure and desired to bring to the notice of the Government of India the resolutions passed on the subject in the previous meetings (*vide* paragraphs 5 (2) and 83 of the minutes of the second and the third meetings respectively) and to reiterate the views contained therein. The Board further drew the attention of the Central and Provincial Governments to the second proviso to the Drugs Rule 44(c) which lays down that

Item (3) of the Agenda :—**Consideration of Government of India's suggestions that the Indian Pharmacopoeial List be included as a standard under the Drugs Rules, 1945 :**

9. The Chairman mentioned that the Government of India had suggested that the Indian Pharmacopoeial List may be recognised as a standard under the Drugs Rules, 1945, and had asked that the suggestion may be placed before the Board for its approval. In the course of the discussion, reference was made to para. 1 of the Government of India, Education, Health & Lands Department, Letter No. 2338-H (C)/43, dated the 26th January, 1944, relating to the formation of the Indian Pharmacopoeial List Committee, which stated that the "List, when approved and issued by the Government of India, will be known as the Indian Pharmacopoeial List and will constitute the official Indian Supplement to the British Pharmacopoeia". The Board desired to bring to the notice of the Government of India that if the Indian Pharmacopoeial List were to constitute the official Indian Supplement to the B. P., as already stated, it would automatically become a standard under the Drugs Rules. However, the Board was of the opinion that it should be recognised as a standard.

10. Incidentally, it was pointed out that on page 182 of the Indian Pharmacopoeial List, mention had been made of "the Sub-Committee" without making any reference to details of it. It was suggested that printing and any other mistakes in the Indian Pharmacopoeial List should be corrected in the next edition.

Item (4) of the Agenda :—**Question of amendments to certain Drugs Rules : Definition of "sale by way of wholesale dealing":**

11. The Chairman pointed out that, representations from the trade requesting that the definition of "sale by way of wholesale dealing" should be amended so as to include sales to hospitals, dispensaries and the medical profession had not been considered favourably in the previous meetings for the reason given in para. 10 of the minutes of the third meeting of the Board, *viz.*, that such a change would bring the medical practitioners into too much competition with the retailers.

12. The Government of India drew the attention of the Board to the above argument which was not considered to be relevant to Drugs Standard Control, and to the fact that by including sales to hospitals, dispensaries and the medical profession in wholesale dealing, there would not be any relaxation in Drug Standard Control, particularly in respect of maintenance of records and supervision of sale. The proposed change, if accepted, would bring the Drugs Rules into consonance with the practice prevalent in the U.K.

13. On the other hand, it was pointed out by Mr. Schroff that if hospitals were allowed to purchase wholesale, there might be scope for black-marketing, corruption and misbranding of drugs in hospitals.

14. It was finally decided, by a majority of six to four, to recommend to the Government of India the following changes in the rules. Drs. Sen, Basu and Guha and Mr. Schroff voted against the changes.

(i) Alter the existing definition of "sale by way of wholesale dealing" to read :

> " 'Sale by way of wholesale dealing' means sale to a person for the purpose of selling again and includes sale to a hospital, dispensary, medical or research institution and to a registered medical practitioner for supply to his own patients. "

(ii) The definition of " retail sale " under Rule 37 (2) should be amended to read :

> " 'Retail sale' means sale to the public for individual consumption, " and brought under Rule 2 as a separate clause.

15. A question was raised by Dr. A. K. Sen whether the above changes in the definitions would lead to consequential changes in other rules or have a repercussion on item (2) under Schedule K to the Drugs Rules. The Board was informed that the

question would be examined and the report circulated to the members of the Board for their consideration at the next meeting of the D. T. A. B.

16. Dr. Sen desired that the attention of the Goverment of India should again be drawn to the fact that the proviso to Rule 37 did not occur in the original draft Drugs Rules and that it had been added without consulting the Board and pre-publication in the Gazette. He also stressed that the Government of India should define the terms "manufacture" and "label" in the Drugs Act, 1940, as has been recommended by the Board in its previous meetings.

17. It was suggested, and the Chairman agreed, that, in future, if the Government of India desired that any amendment of a rule should be considered by the Board in a meeting, full information regarding the amendment should be circulated to the members sufficiently in advance of the date of the meeting. The Board agreed to this.

18. The question of amending the proviso to Rule 96 (3) so as to permit the use of bottles embossed with the names of drugs, "off-set" printed ampoules and containers, was placed before the Board. Dr. Sen stated that in the fifth meeting the Board had already expressed the opinion that the off-set printing of ampoules should not be permitted.

19. Dr. Sen asked on a point of order that the changes in the rules should not be considered by the Board as details of changes had not been circulated to the members in the agenda. The Chairman ruled that the changes in the rules could be considered by the Board even though details regarding them had not been circulated to the members in the agenda. He stated that the question for the consideration of the Board was whether the proviso to Rule 96 (3) should be amended. Thereupon Mr. Schroff moved the following :—"In view of the fact that the changes intended to be made in the Drugs Rules were not circulated to the members concerned and hence, they require time for reconsideration of their previous decisions, it is resolved that the consideration of the changes in the rules should be deferred to another meeting of the Board or be postponed so as to allow the members more time for consideration of the intended changes in the rules. The motion was seconded by Dr. A. K. Sen, and votes being taken, Drs. Basu, Guha, Sen and Mr. Schroff voted for it, but was lost by the second or casting vote of the Chairman."

Amendment of the proviso to Rule 96 (3) so as to permit the use of bottles embossed with the names of drugs, "off-set" printed ampoules and containers :

20. The above amendment was taken up for consideration. It was pointed out that if the use of containers embossed with the names of drugs was not permitted, the supply of a whole range of products, such as eye ointments, etc., in collapsible tubes and tablets, etc., packed in wooden and tin containers on which the labels cannot be easily affixed, will be at a standstill on the date, the Drugs Rules come into force. The main objection was to the use of glass containers, both ampoules and bottles, etched or sandblasted with the names of items, in which case, there was the possibility of their getting mixed up in the factories with the result that the containers embossed with one name may be filled up with the wrong substance. After discussion, it was agreed that, excepting for glass containers, there was no objection to the use of other containers being etched or indelibly printed with the names of drugs. "Off-set" printing of ampoules was, however, not agreed to, as all the details required could not be marked clearly on the ampoules. It was recommended that the last line in the proviso to Rule 96 (3) should be amended to read "etched, painted or otherwise indelibly marked on *any glass container.*"

21. The Board agreed to recommend to the Government of India the following changes :—

(i) In Rule 100 (2) (a) and 100 (3)—After the words "British Pharmaceutical Codex", *add* "or in any other prescribed pharmacopoeia".

(ii) In Rule 101 (5), line 2—After the words "British Pharmaceutical Codex" *add* "or in any other prescribed pharmacopoeia". In line 7 of the same rule, after the word "label" and before the words "the proportion..", *insert* "the quantity of alcohol or".

22. The suggestion that labels, as required by Rule 102, are not necessary in the case of silk, linen and cotton threads, was not agreed to as such threads are used as sutures.

23. The impracticability of testing for sterility, surgical ligatures and sutures sterilised before use in hospitals as required by Rule 102, was explained to the Board and it was suggested that the words "and tested for sterility by the processes prescribed by Rules under the Drugs Act, 1940" in that rule should be omitted from the labels on non-sterile surgical ligature and suture. A counter-suggestion was put forward that the words "not to be used for operations upon the human body unless efficiently sterilised and tested for sterility by the processes prescribed by rules under the Drugs Act, 1940, may be deleted from the labels. The former suggestion was agreed to, while the latter was defeated by a majority of two votes.

Technical literature in packings of medicines :

24. Rule 106, as it stands, does not allow the inclusion in the packings of medicines technical literature in regard to the treatment of diseases mentioned in Schedule J to the Drugs Rules. Literature explaining the dosage, administration and reactions of drugs like sulphonamides, penicillin, etc., used in the treatment of venereal diseases, is necessary for the guidance of the medical profession. It was therefore suggested to the Board that a provision may be made on the lines of the Venereal Diseases Act of 1917 of the U.K., exempting from the provisions of the Act and the rules, such publications indicating the treatment, dosage and reactions as are sent to medical practitioners eligible for registration or to wholesale and retail chemists for the purpose of their business. In opposition to this suggestion, it was argued that, the rule, as such, would not prevent a technical pamphlet from stating that a certain drug is indicated in the *rational treatment of venereal disease*, etc., and all that the rule prohibited was the inclusion of pamphlets claiming to be *cures* for the diseases mentioned in Schedule J or those claiming to assist in securing miscarriage in women.

It was pointed out by Dr. A. K. Sen that Rule 106 applies only to the labelling and packing of the medicines and does not preclude technical pamphlets from being sent direct to the medical practitioners, hospitals, etc. Pamphlets, when included in packings of drugs, are likely to reach the hands of people, who may take recourse to self-medication. It was finally decided that the question should be taken up at the next meeting and that, in the meantime, the relevant portions from the Venereal Diseases Act of 1917 of the U. K. should be circulated to the members.

25. The Board recommended that the words "miscarriage of women" in Rule 106 should be amended to "miscarriage in women".

Printing of proper and proprietary names of Schedule C items on labels :

26. An enquiry was made of the Board whether it was the intention that in labelling Schedule C items, the proprietary name should precede the proper name as required by Rule 109 (1) (a). It was clarified that the object of the rule is to ensure that the trade and proper names appear side by side on the label and that, as long as one name was not less conspicuous than the other and followed *immediately after* the other, it was immaterial which one was printed first.

Question of labelling vitamin preparations for oral use with the words 'Not to be injected'.

27. According to the labelling provisions under item D of Part XI of Schedule F to the Drugs Rules, 1945, it is necessary that preparations for *oral* use such as Colloidal Calcium with Vitamin D and Liquor Adrenaline Hydrochloride, etc., should be labelled "Not to be injected".

It was mentioned that since there were positive provisions for labelling parenteral drugs, there was no need for negative instructions in case of medicines in a form not

to be administered parenterally. On the other hand, it was argued that in the case of multivitamin tablets, etc., which are used for the dual purpose of oral and parenteral administration, it would be necessary to distinguish the nature of the preparation by labelling. A suggestion that the words " For oral use only " may be substituted for the words " Not to be injected " was not agreed to as Cod Liver Oil and other substances are administered by routes other than oral. It was finally agreed that the words 'Not to be injected' should be substituted by " Not for parenteral administration ".

28. It was agreed that under Schedule H to the Drugs Rules, the words " (See Rule 65 (8) and (10)) " should be substituted by "(See Rule 65 (9) and (11))".

Item (5) of the Agenda :—**Preparation of draft rules regulating the control of advertisements relating to medicines :**

29. (*a*) Copies of the Provincial Legislations of Bihar, Orissa and N. W. F. P. for the control of advertisements were circulated with the agenda. It was suggested that, in view of the desire of the Government of India to obtain a set of model rules for the guidance of the Provinces, a Sub-Committee of the Board may be formed for the purpose.

(*b*) The absence of legislation to control advertisements in the centrally-administered areas of the Government of India was pointed out and it was emphasised that the Government of India should ensure that the various provincial legislations are uniform and comprehensive.

(*c*) The Board also observed that, while under the Orissa Bill advertisements of cures for all the diseases mentioned in Schedule J could be prohibited, the N. W. F.P. and Bihar Acts prohibit only advertisements relating to cures for venereal diseases and abortifacients.

(*d*) It was suggested to the Government of India that they should inform the Board of the particular provincial legislation on which the model rules are to be based. In the meantime, the Secretary was asked to circulate to the members the relevant extract from the U. K. and U. S. A. legislations and the New and Non-Official Remedies.

Item (6) of the Agenda :—**Consideration of changes proposed by Government of India in Forms Nos. 6, 8, 14A, 19, 24 and 27 under Schedule A to the Drug Rules :**

30. Forms Nos.3, 6, 8, 14A,19, 24 and 27 which are used by the public for the application of various licences should indicate how the fee in each case should be remitted to the licensing authority. The suggested changes in the forms for this purpose, *vide* Appendix IV were agreed to by the Board.

Item (7) of the Agenda :—**Consideration of resolutions (Appendix V) to be moved by Mr. M. L. Schroff :**

31. An enquiry was made if the first resolution proposed to be moved by Mr. Schroff was within the scope of the functions of the Board. The Chairman ruled that the resolution did not fall within the jurisdiction of the Board.

32. In moving the second resolution, Mr. Schroff said that the intention was to ascertain whether cosmetics and hair oils claiming to be cures for ailments such as failing hairs, baldness, rough skin, etc., come within the definition of "drug" in the Drugs Act. The original Canadian definition of "drug" on which the present definition of " drug" in the Drugs Act is based, did not include cosmetics and toilet goods. After discussion, it was decided to recommend to the Government of India that the definition of "drug" in the Act should be amplified to include cosmetics and toilet goods and that a draft definition suggested by Dr. Sen and Mr. Schroff should be circulated to the members to enable them to take up the question at the next meeting.

33. The Chairman pointed out that the third resolution was not clear and involved interpretation of the existing rules. As the Board had already agreed to the question of drafting model legislation for controlling advertisements of medicines, Mr. Schroff agreed to drop the resolution.

Item (8) of the Agenda :— **Any other business allowed by the Chairman :**

34. (*a*) The representation received from the All-India Private Medical Practitioners' Association was considered. A deputation of these practitioners waited on the Board. It was decided that the views of the Association should be ascertained through their representative.

(*b*) The Chairman of the Association, Mr. Sultan Yar Khan, stated that the unregistered medical practitioners wanted Schedule H to the Drugs Rules to be modified to enable them to prescribe sulphonamides to their patients. He added that the sulphonamides had become a common remedy for diseases such as cold, pneumonia, etc., and that the unregistered medical practitioners and the poorer section of the public would be hard-hit if the restrictions on the use of sulphonamides in Rule 65 (9) continue.

(*c*) It was considered that the question should be examined in the next meeting and that, in the meantime, copies of the representation be circulated to the members.

35. The Board was asked to give its opinion whether in disclosing the formula and composition of ingredients in the case of patent and proprietary medicines which are not registered at the Central Drugs Laboratory, it would be necessary to specify the inert and excipient materials, including colouring matter, binders and solvents, and their composition. It was agreed that it would be sufficient if, in accordance with the explanation given under Sections 10 and 18 of the Act, the names and compositions of the potent and poisonous ingredients contained in such patent and proprietary medicines are specified. The term "approximate statement of the composition of the medicine" was considered to relate to the proportion of quantities of the potent and poisonous ingredients in the drugs and it was not necessary to specify the details regarding the inert substances.

36. Government of India, Department of Health, letter No. 18-3/46-D, dated the 22nd February, 1947 (Appendix VI), forwarding the opinions of the Provincial Governments on the recommendations of the Board in regard to the control of Homeopathic medicines under the Drugs Act and Rules was taken up for consideration. It was not considered practicable to control the quality of homeopathic drugs or to standardise the mother tinctures used by homeopathic practitioners. The Board agreed that there were no grounds to alter their previous recommendations on the subject.

37. A representation from the Pharmaceutical & Allied Manufacturers' & Distributors' Association, Ltd., that the printing of cautionary notices on the labels of poisonous preparations, *vide* Rule 98 should be allowed to be done in black ink instead of in red ink, was considered. Despite the plea of the Association that printing in red ink will raise the cost of labels, the Board was unanimous in its view that, considering the low level of education among the great majority of the consumers in India, the notices should be printed in red ink. The Board was against any exemption being granted for the printing of cautionary notice in black ink in the case of Insulin as requested by the Association and insisted that the printing of cautionary notice for Insulin should be in the mandatory colour, though other details on the label may be in any other colour.

38. A vote of thanks to the Chairman was proposed by Dr. Ghosh and seconded by Dr. Basu.

JIVRAJ N. MEHTA,
Director-General of Health Services,
Chairman, Drugs Technical Advisory Board.

NEW DELHI;
20th January, 1948.

APPENDIX I

OBJECTIONS OR SUGGESTIONS RECEIVED BY THE GOVERNMENT OF INDIA IN RESPECT OF THE DRAFT AMENDMENTS TO THE DRUGS RULES, 1945, RELATING TO PENICILLIN AND BACTERIOPHAGES.

Copy of letter No. *Nil*, dated the 30th September, 1946, from the Pharmaceutical & Allied Manufacturers' & Distributors' Association, Limited, Bombay, to the Health Department.

Drugs Rules, 1945.

Further to our earlier letter on the subject, para. 108 (1), the legislation introduced for Penicillinised still incomplete. In our earlier letter we had queried whether lozenges and ointments need be packed in sterilised glass containers. Tablets and wafers of Penicillin are now available, and there does not appear to be any real reason why it should be laid down that these should be packed in sterilised glass containers. The present special packing devised by the manufacturers of these products appears to be eminently satisfactory.

We would recommend rather that the wording be used : "packed in containers which do not aid production of Penicillinase." We should be glad if this matter is given consideration.

Copy of letter No. *Nil*, dated the 28th October, 1946, from the Pharmaceutical & Allied Manufacturers' & Distributors' Association, Limited, Bombay, to the Health Department.

Drugs Rules, 1945.

We would refer to the Drugs Rules 1945, Part IX "Provisions Applicable to Penicillin" Rule 4 which states that "The potency so determined shall be expressed in units per milligramme in the case of solid preparations."

The practice of expressing the potency of penicillin in units per milligramme has been adopted by one or two American firms and by one of the British factories, but we do not think it is yet a universal practice. However, if the Government of India insist on this being done it will, of course, have to be done, but we would suggest for the serious consideration of the Drugs Technical Advisory Board that it is perhaps absurd to insist that units per milligramme should be stated in the case of penicillin tablets, chewing wafers (troches) and more particularly in the case of ointments for tropical use. So long as the total number of units of penicillin is clearly stated per tablet, per troche or per gram of ointments we think that this is all that is necessary from a practical point of view and it would be fantastic to try and reduce an ointment to terms of units per milligramme when it is quite impossible to regulate the exact dosage.

We should be grateful if this matter could have the early attention of the Board so that the manufacturers abroad may know exactly the conditions they have to comply with.

Copy of letter No. 04M/d/556, dated the 27th November, 1946, from the Bengal Chemical & Pharmaceutical Works, Ltd., Calcutta, to the Health Department.

Sub. :—Draft amendments to the Drugs Rules, 1945, as published in the extraordinary issue of the Gazette of India, dated the 24th August, 1946.

Referring to the above notification we beg to make the following observations and hope these will receive proper consideration :—

Part XII.—Provisions applicable to the production of Bacteriophages.

We suggest that the insertion of the following clauses is necessary for safeguarding the quality :—

(*a*) No antiseptic as preservative should be added to the Bacteriophage.
(*b*) Filled containers, *i. e.* ampoules must be incubated at 37°C. for a week.

Precaution as per clause (*b*) above is considered necessary to eliminate those that are contaminated or are liable to cause secondary growths.

Re : Clause 8.—Tests.

We are of opinion that the test for sterility prescribed here is unnecessary in view of the following considerations :—

(*a*) Bacteriophages are for oral administration only.
(*b*) Assuming that no preservatives are used and Bacteriophage itself being made up either of broth or peptone, any contamination or secondary growth occurring after filling in of the ampoules will be self evident and the preparation will be either cloudy or show a deposit.

Copy of D. O. Letter No. 6618, dated te 18th December, 1946, from the H. M. Trade Commissioner at Delhi, to the Secretary to the Health Department, Govt. of India, New Delhi.

When the Draft Drug Rules were published in the Gazette of India last August we drew them to the attention of the agents of certain United Kingdom manufacturers, and you may be interested to see the enclosed extract from the comments of one of the U. K. firms.

In the first place the whole of the proposed Rules are very largely out of date by reason of their having been based on the old Therapeutic Substances Amendment (No. 2) Regulations, 1944, S R & O 1944, No. 922. As you know, these regulations were replaced in March last, by S R & O 1946, No. 467. It seems quite wrong for the Indian Government to issue new Regulations which at the time they come into operation are three years out of date, especially when they relate to a substance such as penicillin, regarding which knowledge is so rapidly increasing, thus the requirement that the penicillin salt used for making solutions for injection should contain not less than 150 units mgm absurd, although of course it would cause no inconvenience to any one but the unfortunate patient. Again, the test for freedom from pyrogenic substances definitely needs amendment and should agree with the test at present in force in this country, which was agreed without Ministry of Health and the M. R. C. before being included in the Order.

Our main objection to the present proposals is that they do not make it clear what preparations of penicillin are covered. Apparently for example a Suspension in oil and beeswax is not included in the definition of "Preparation of penicillin." One assumes that ointments are not included, but the position of preparation such as lozenges and solution tablets is obscure. Even our own Regulations are hazy on the position of the Suspension but we do know that the Ministry of Health intended it to be included but did not intend to include any non-injectable preparations. If the same intentions obtain in India, it is suggested that the proposed Order be amended so as to make them clear.

If, for example, the suspension is intended to be included, then certain of the tests will need to be modified since as at present drafted they call for the preparation of an aqueous solution. This of course is a physical impossibility in the case of oily preparations.

From Dr. S. S. Aiyar, Chief Chemist, Central Revenue Control Laboratory, New Delhi.

I have the following comments on the regulations regarding Penicillin :—

Section I (iv).

The definition of penicillin should make a provision for this material if it is obtained from any other organism and may be even by synthesis.

The definition should also include suspensions of penicillin in any medium (*e.g.*, calcium penicillin in oil) and penicillin creams, pastes, lozenges, etc.

Section 4 and further.

(1) Rule 21 (*b*) permits the Central (or Provincial) Government to authorise any person to act as licensing authority and Rule 22 permits the delegation by this officer of any or all powers exercised by him to any of his subordinates. Although Rule 26 contemplates testing of samples of drugs in an attached laboratory, there is nothing in the rules to prevent the licensing authority from disregarding any advice tendered by the laboratory and issue licences.

(2) Rule 31 specifies that the standards prescribed in Schedule C and C (i) shall be followed for some biological and other special drugs. Penicillin being a drug coming in this group, it stands to reason that standards and tests should be prescribed by the Government on the advice of the Drugs Technical Advisory Board instead of being left (as envisages) to be determined by the licensing authority. As regards other drugs, Rule 124 prescribes the adoption of standards specified in B.P., B.P.C., U.S.P. or N.F.

(3) As it is there is no provision in the rules for automatic enforcement of uniform standards in all Provinces unless the standards and tests form part of the rules. The leaving of the decision to the licensing authority causes a loophole in permitting varying standards and methods in different parts of the country.

(4) Under tests for potency.

Instead of "by a method approved by the licensing authority" insert "by the biological method of assay described below" and add actual details of the assay as an additional para.

E.G.—Cylinder plate and Broth-dilution methods.

Wherever the word C.C. has been used, the word millilitre should be substituted.

Section 5 (i).

Will medical men please state whether penicillin (crude filtrate) and penicillin (dried crude filtrate) with the minimum potencies mentioned against them in this rule have any therapeutic use or value at all ?

Section 5 (ii).

The B.P. states that penicillin (Calcium or sodium) to be used for the preparation of parenteral injections should contain not less than 900 units per mgm. The draft rule puts the figure at 150 units. The lowering of the standard is likely to result in the use in this country of material having harmful side reactions.

Section 8.

The draft rule differs from the English regulations in taking twice the number of units for injection and stipulating that rise of temperature should not be above a certain figure, this figure again being twice the value given in the English regulations. Is the alteration deliverate and is the rise in temperature expected to be directly proportional (within limits) to the number of units injected ?

Storage.

There are no instructions regarding the precautions to be observed in the storage of penicillin (dry salts) and penicillin solutions. Please specify limit of temperature

APPENDIX II.

Copy of letter No. 213, dated the 22nd January, 1947 from the Secretary, Indian Chemical Manufacturers' Association, Calcutta, to the Secretary to the Government of India, Department of Health, New Delhi.

UNDER CERTIFICATE OF POSTING.

Re.: DRUGS RULES, 1945.

I am directed by the Committee of the Indian Chemical Manufacturers' Association to invite reference to the notification No. 28-10/45H (1), dated the 18th December, 1946, issued by your department. The Committee of the Association note in this connection that the Government of India propose certain amendments to the Drugs Rules, 1945, by inserting the rule 3A according to which the Central Research Institute at Kasauli will carry on the functions of the laboratory under the Drugs Rules in respect of the following class of drugs:—

1. Sera.
2. Solution of serum proteins intended for injection.
3. Vaccines.
4. Toxins.
5. Antigens.
6. Anti-toxins.
7. Penicillin.
8. Sterilised surgical ligature & Sterilised surgical suture.
9. Bacteriophages.

The Committee of the Association regret to note that the Government of India propose to give the necessary powers of testing Indian made preparations, especially Vaccines and Sera, to the Central Research Institute at Kasauli in spite of the fact that several representations had been made by the Association pointing out that such an arrangement would be unfair from the point of view of the industry in view of the manufacturing activities of the Government Institutions. In this connection I am directed to invite reference to the representation, dated the 2nd August, 1945, which had been addressed to the Government of India by the Association on the Drugs Rules, 1944. The Association had pointed out in that representation that the Central Research Institute at Kasauli was engaged in the manufacture and sale of certain class of drugs, like Sera and Vaccines, etc., and was actually competing with the pharmaceutical manufacturers in that field. Therefore, it was strongly felt that the Central Research Institute at Kasauli being a manufacturing organisation should not be entrusted with the testing of Indian made drugs, unless it discontinued its manufacture and sale of similar products. This matter had further been explained by the representatives of the Association when they met the Drugs Technical Advisory Board on 24th of January, 1945, at the offices of the Director General of Indian Medical Service at New Delhi. It had been clearly pointed out at the meeting that unless the Government institutions, like Kasauli Institute, gave up their manufacturing activities in such fields of manufacture, *viz.*, sera, vaccines, etc., where they competed with the indigenous pharmaceutical industry, it would be unfair from the point of view of the industry that such institutions should be empowered to test the sera and vaccines manufactured by the industry. The Committee of the Association consider it hardly proper that an organisation which is interested in manufacturing and supply certain medicines should be authorised to test the products of other manufacturers competing with that organisation in the same field. The Committee further appreciate that it may be considered necessary for the organisation which is given the function of the laboratory under the Drugs Rules to have some manufacturing experience, but it is essential that this experience must only be confined to research activities or manufacture only on a non-commercial scale. The proposed arrangement, in the opinion of the Committee, would definitely go against the interests of the Indian manufacturers, whose products will be tested by an organisation which is itself a manufacturing organisation and competes with the industry.

In this connection, the Committee of the Association would further reiterate the demand made by the industry for the past several years to the effect that such Government institutions like the Central Institute at Kasauli or the Haffkine Institute in Bombay, must confine their activities purely to research work or such lines of manufacture which are not developed in this country instead of competing with the industry which is already established. It is a matter of regret, however, that the activities of the Government institutions in such fields of manufacture, like vaccines and sera, where the industry is fully capable of meeting the indigenous demand, are increasing every day to compete with the products of the indigenous manufacture. The Committee of the Association strongly feel that the Government of India must give their early consideration to this matter and ensure that such competition in the field of manufacture is removed as early as possible in the interest of the Indian drug industry.

With regard to the notification referred to above the Committee of the Association would, therefore, suggest that the provision made therein should not be made effective till such time that the Government institutions positively restrict their manufacturing activities to avoid any competition with the indigenous industry. Unless this is done and the manufacture on a commercial scale of vaccines and sera, etc., produced by the industry is discontinued in the Kasauli Institute, the Committee of the Association would strongly protest against the procedure of empowering the Kasauli Institute to test indigenous products. The Committee of the Association trust that careful consideration would be given by the Government of India to this matter and such institutions which manufacture and sell the products which are manufactured by the industry will not be given the functions of the testing laboratories under the Drugs Rules on principle.

The Committee of the Association trust that the representation would receive sympathetic consideration at the hands of the Government of India. If necessary, the representatives of the Association will be glad to meet the Government representatives to discuss the matter personally with them.

APPENDIX III

STATUTORY RULES AND ORDERS, 1946, No. 467.

THERAPEUTIC SUBSTANCES.

THE THERAPEUTIC SUBSTANCES AMENDMENT REGULATIONS, 1946, DATED MARCH 29, 1946, MADE BY THE JOINT COMMITTEE CONSTITUTED UNDER SECTION 4 (1) OF THE THERAPEUTIC SUBSTANCES ACT, 1925 (15 & 16. Geo. 5. c. 60).

The Joint Committee constituted under sub-section (1) of section 4 of the Therapeutic Substances Act, 1925 (in these regulations called "the Act"), in exercise of the powers conferred on them by sections 1 and 5 of the Act, after consultation with the Advisory Committee constituted under sub-section (2) of section 4 of the Act, hereby make the following regulations:—

1.—(1) These regulations may be cited as the Therapeutic Substances Amendment Regulations, 1946, and the Therapeutic Substances Regulations, 1931 to 1944, and these regulations may be cited together as the Therapeutic Substances Regulations, 1931 to 1946.

(2) These regulations shall come into force on the first day of April, 1946.

2.—(1) In these regulations the expression "the principal regulations" means the Therapeutic Substances Regulations, 1931 (S.R. and O. 1931, No. 633).

(2) The Interpretation Act, 1889 (52 & 53 Vict. C. 63) applies to the interpretation of these regulations as it applies to the interpretation of an Act of Parliament.

3. The Therapeutic Substances Amendment (No. 2) Regulations, 1944 (S.R. and O. 1944 No. 922), are hereby revoked:

Provided that this revocation shall not affect anything duly done or suffered, or any right, privilege, obligation or liability acquired, accrued or incurred, under the said regulations, and in particular any licence granted thereunder shall continue in force and shall have effect as if it were a licence granted under the principal regulations as amended by these regulations for the manufacture of penicillin.

4. The following substances shall, in substitution for the substances added to the schedule to the Act by regulation 3 of the Therapeutic Substances Amendment (No. 2) Regulations, 1944, be added to the schedule to the Act as being substances the purity or potency of which cannot be adequately tested by chemical means, namely, any anti-infective acid produced by *Penicillium notatum*, whether obtained from *Penicillium notatum* or not, any salt or derivative of any such acid and any solution containing any such acid, salt or derivative, being an acid, salt or derivative, or a solution thereof, prepared for parenteral injection.

5.—(1) The substances added by regulation 4 of these regulations to the schedule to the Act shall be issued only in the form of a dry salt or other dry substance, or in a form approved by the licensing authority.

(2) The expression "Penicillin" in the principal regulations as amended by these regulations means any such substance as aforesaid in any such form as aforesaid.

6. In the proviso to paragraph (1) of regulation 9 of the principal regulations (which provides that a container of surgical ligature or suture need not be of glass) after the word "suture" there shall be inserted the words "or of penicillin".

7. Sub-paragraph (*c*) of paragraph (3) of regulation 10 of the principal regulations (which requires that in certain circumstances the label of a therapeutic substance shall contain a statement that the substance has passed a test for maximum toxicity) shall not apply to penicillin.

8. The following words shall be inserted at the end of regulation 12 of the principal regulations:—

"Provided that in the case of penicillin in any form such of the tests may be applied at such earlier stage in the manufacture as may be approved by the licensing authority in respect of penicillin in that form."

9.—(1) The following paragraph shall be inserted in regulation 15 of the principal regulations (which provides for the making of tests of sterility in the case of the substances therein specified) after paragraph (*f*):—

"(*g*) penicillin".

(2) In proviso (i) to the said regulation (which proviso provides for the application of the said tests, in certain cases, with modifications) after the word "insulin" there shall be inserted the words "and penicillin".

10. The following schedule shall be substituted for the seventh schedule to the principal regulations:—

SEVENTH SCHEDULE

PENICILLIN

PROPER NAME.

1. The proper name of penicillin is "penicillin" followed by a word or words, indicating the nature of the preparation, as, for example, "penicillin (sodium salt)".

STANDARD PREPARATION

2. The standard preparation is a quantity of dry penicillin salt kept at the National Institute for Medical Research, Hampstead, London.

UNIT OF STANDARDISATION

3. The unit of penicillin for the purpose of these regulations is the activity contained in such an amount of the standard preparation as may be indicated from time to time by the Medical Research Council as the quantity exactly equivalent to the unit accepted for international use.

STRENGTH.

4.—(1) Penicillin shall be tested for potency by comparative tests in relation to the standard preparation, by a method approved by the licensing authority. The potency so determined shall be expressed in units per milligramme in the case of penicillin in solid form and in units per c. c. in the case of solutions.

(2) Penicillin with a potency, in the case of penicillin in solid form, of less than 300 units per milligramme, or, in the case of a solution, of less than 2,000 units per c. c. shall not be issued :

Provided that the licensing authority may authorise with or without conditions, the issue for specified purpose of penicillin which does not satisfy the said standards.

TESTS FOR FREEDOM FROM ABNORMAL TOXICITY

5. Penicillin shall be subjected to the following test for absence of abnormal toxicity :—

A quantity of the penicillin containing not less than 1,000 units, dissolved, in the case of penicillin in solid form, in a volume not exceeding 0·5 c.c. of a watery solution, shall be injected intravenously into each of five normal mice each weighing approximately 20 grammes.

The sample shall be treated as having passed the test if either—

(*a*) the injection does not cause death in any of the mice within twenty-four hours from the injection, or

(*b*) the injection having caused death in one only of the mice within that period, further such injections in five other such mice do not cause the death of any of those mice within twenty-four hours from the injection.

TESTS FOR FREEDOM FROM PYROGENIC SUBSTANCES

6. Penicillin shall be subjected to the following test for absence of pyrogenic substances :—

There shall be injected intravenously into each of three normal healthy rabbits each weighing not less than 1.5 kilograms a quantity of the penicillin containing not less, in the case of each rabbit, than 2,000 units per kilogram of the rabbit's weight, dissolved, in the case of penicillin in solid form, in not more than 5 c.cs. of water or physiological saline. The body temperature of the rabbits shall be recorded either continuously from one hour before, until three hours after the injection, or at least once during the hour before, and three times in the three hours after, the injection, one of which shall be between seventy-five and ninety minutes after the injection. The sample shall be treated as having passed the test if the average maximum increase of temperature shown by the three rabbits does not exceed 0·6°C.

CONTAINER

7. The materials of which a container (including the closure) of penicillin are made shall be materials as to which the licensee has satisfied himself that they do not lead to the destruction of penicillin.

LABELLING

8. If penicillin as issued for sale is mixed with any substance the label on the container shall state the nature of that substance and the minimum number of units of penicillin per gramme of the mixture in the case of penicillin in solid form or per c.c. thereof in the case of a solution.

These regulations were made by the aforesaid Joint Committee this twenty-ninth day of March, nineteen hundred and forty-six.

ANEURIN BEVAN
J. WESTWOOD
WILLIAM GRANT
} MEMBERS OF THE JOINT COMMITTEE.

F.F. MARCHBANK, Clerk to the Joint Committee.

APPENDIX IV

PROPOSED AMENDMENTS TO FORMS UNDER SCHEDULE A TO THE DRUGS RULES, 1945.

Form No.	Heading.	Amendment or addition.
Form 3 .	Application for a certificate of registration of a patent or proprietary medicine. (Rule 9)	The following has been substituted in place of the existing para. 4 : "4. A fee of rupees fifty has been credited to Government under the head of account "XXVII —Medical—Miscellaneous—Fees under the Drugs Rules, 1945—Central"—*Vide* treasury receipt attached."
Form 6 .	Application for renewal of a certificate of registration of a patent or proprietary medicine. (Rule 16 (2))	An addition has been made at the end as follows :— "2. A fee of rupees fifty has been credited to Government under the head of account "XXVII —Medical—Miscellaneous—Fees under the Drugs Rules, 1945—Central"—*Vide* treasury receipt attached."
Form 8 .	Application for a licence to import biological and other special products specified in Schedule C and C (1) to the Drugs Rules, 1945. (Rule 24)	An addition has been made at the end as follows :— "2. A fee of rupees ten has been credited to Government under the head of account "XXVII— Medical—Miscellaneous—Fees under the Drugs Rules, 1945—Central"—*Vide* treasury receipt attached."
Form 14-A .	Application from a purchaser for test or analysis of a drug under Section 26 of the Drugs Act, 1940. (Rule 47)	An addition has been made at the end as follows :— "7. A fee of rupees.....—*Vide* Schedule B to the Drugs Rules, 1945—has been credited to Government under the head of account "XXVII —Medical—Miscellaneous—Fees under the Drugs Rules, 1945—Central"—*Vide* treasury receipt attached."
Form 19 .	Application for a licence to sell, stock or exhibit for sale and distribute drugs. (Rule 59)	An addition has been made at the end as follows :— "5. A fee of rupees five/ten has been credited to Government under the head of account "XXVII —Medical—Miscellaneous—Fees under the Drugs Rules, 1945—Central"—*Vide* treasury receipt attached."
Form 24 .	Application for licence to manufacture drugs other than biological and special products. (Rule 69)	An addition has been made at the end as follows :— "4. A fee of rupees twenty has been credited to Government under the head of account "XXVII —Medical—Miscellaneous—Fees under the Drugs Rules, 1945—Central"—*Vide* treasury receipt attached."
Form 27 .	Application for grant or renewal of a licence to manufacture biological and other special products. (Rule 75)	An addition has been made at the end as follows :— "4. A fee of rupees twenty and an inspection fee of rupees one hundred have/An inspection fee of rupees thirty has been credited to Government under the head of account "XXVII Medical— Miscellaneous—Fees under the Drugs Rules, 1945 —Central"—*Vide* treasury receipt attached."

APPENDIX V

Resolution to be moved by Mr. M.L. Schroff, A.B. Hons. (Cornell), M.S. (M.I.T) at the Sixth Meeting of the Drugs Technical Advisory Board to be held on the 25th February, 1947.

1. Resolved that a declaration be obtained from the manufacturers of indigenous medicines in a form to be prescribed for the purpose by the Board to the effect that the medicines manufactured by them do not contain any ingredients covered by the Drugs Act, 1940 and Drugs Rules, 1945. In the alternative, the indigenous manufacturers may be asked to give a declaration of all those medicines which they manufacture and which contain any of the constituents covered by the Drugs Act, 1940 or the Drugs Rules, 1945.

2. Resolved that all preparations including cosmetics and hair oils and devices which are advertised for the cure or mitigation of any disease or symptom whatsoever should be regarded as coming within the purview of the Drugs Act, 1940 or the Drugs Rules, 1945.

3. Resolved that the publication of any advertisement claiming to mitigate or cure any of the diseases mentioned in Schedule J of the Drugs Rules may be interpreted as if the advertisement was included as part of the literature of the drug in question and hence, deemed to have violated the Drugs Rules.

APPENDIX VI

No. 18-3/46-D

GOVERNMENT OF INDIA.

DEPARTMENT OF HEALTH.

NEW DELHI, The 22nd February, 1947.

FROM

HARBANS SINGH, ESQUIRE,

ASSISTANT SECRETARY TO THE GOVERNMENT OF INDIA,

To

THE SECRETARY,

DRUGS TECHNICAL ADVISORY BOARD,

C/o THE DIRECTOR GENERAL, INDIAN MEDICAL SERVICE, NEW DELHI.

Subject :—CONTROL OF HOMEOPATHIC MEDICINES UNDER THE DRUGS ACT AND RULES.

SIR,

I am directed to refer to the correspondence resting with your U. O. Memorandum No. 6/45-DAB, dated the 9th May, 1946, and to enclose herewith copies of the communications the details of which are given in the margin containing the opinions of certain Provincial Governments on the recommendations of the subcommittee on the control of homeopathic medicines under the Drugs Act and Rules. The other Provincial Governments have agreed with the recommendations of the sub-committee. I am to request that the opinions of the Provincial Governments forwarded herewith may kindly be placed before the Drugs Technical Advisory Board at their forthcoming meeting and their comments communicated to the Government of India in due course.

1. Letter No. 32005-G. 1/46-1-P. H., dated the 18th December, 1946, from the Government of Madras, with enclosures.
2. Letter No. 4121/33-H, dated the 19th September, 1946, from the Government of Bombay.
3. Letter No. Medl. 2D-5/45(*a*), dated the 21st September, 1946, from the Government of Bengal, with enclosures.
4. Letter No. A/588/V-667/46, dated the 7th January, 1947, from the Government of the United Provinces.
5. Letter No. $\frac{25781/HM.}{19/168-III}$ dated the 6th September, 1946, from the Government of the North-West Forntier Province.
6. Letter No. 4858-C/46, dated the 12th September, 1946, from the Government of Sind.

I have the honour to be,

SIR,

Your most obedient servant,

Sd/. Harbans Singh,

Assistant Secretary.

Enclosure :—Noted in margin.

Copy of Madras Government letter No. 32005/G. 1/46-1-PH., dated the 18th December, 1946, to the Secretary to the Government of India, Department of Health, New Delhi.

Control of Homeopathic medicines under the Drugs Rules, 1945.

With reference to your letter No. F. 18-3/46-D, dated the 12th June, 1946, I am directed to state that this Government agree with the recommendations made in paragraph 7(*a*) and (*c*) of the report of Sub-Committee appointed by the Drugs Technical Advisory Board. As regards the recommendations in paragraph 7(*b*) this Government are of opinion that no useful purpose will be served by licensing the shops and factories in view of the recommendations of the Sub-Committee in paragraph 7(*a*) of the report. I am to enclose in this connection copies of the letter on the subject from the Surgeon-General with this

Copy of letter from the Surgeon-General with the Government of Madras, No. 39506-4-P.W., date. the 18th July, 1946.

Drugs Control of Homeopathic medicines under the Drugs Rules, 1945, Government Endt No. 32005-G-2/46-1-P.H., dated the 20th June, 1946.

I agree with the recommendations of the Sub-Committee of the Drugs Technical Advisory Board that the quality of Homeopathic medicines should not be included in the control of drugs under the Drugs Rules. The recommendation contained in 7(*b*) appears to be in conflict with the previous recommendation regarding the licensing of manufacture and sale of Homeopathic drugs. I therefore suggest that Homeopathic drugs may be excluded from the provisions of the Act by a suitable entry in the "Exemptions" under Schedule K of the Rules provided they are distinctly marked to indicate that they are to be exclusively for use in accordance with the Homeopathic system of medicine.

The Principal School of Indian Medicine, Madras, has not furnished his remarks.

Copy of letter from T. Janakiram, M. B. Ch. B., (Edin), 9, Gopalakrishna Road, Thyagarayanagar Madras, dated 14-9-1946.

Drugs Control of Homeopathic medicines under the Drugs Rules, 1945.

I thank you for your letter dated 9th September, 1946, asking for my views on the recommendations of the sub-committee of the Drugs technical Advisory Board. I beg to forward my opinion below :—

(1) With reference to the statement of sub-committee that they have interviewed a good many Homeo physicians and manufacturers, I have to observe that so far as I am aware of, none of the leading Homeopaths in this presidency had been interviewed or consulted. Perhaps the physicians and manufacturers referred to, were all outside this province.

(2) The commitee has appreciated the difficulties in examining the quality and the quantity of the actual drug part of Homeo medicines. They themselves abandoned the idea of exercising the control over them.

(3) According to the report of the committee most of the Homeo medicines used in India are imported from U.S.A. or U.K., as such the actual manufacture in India is in its initial stages, and even that, is confined mostly to the province of Bengal. I am aware that just now certain companies in this presidency are trying to open manufactories of Homeo medicines on a modest scale. The nature of the manufacture of Homeo medicines does not require elaborate apparatus or extensive labour. In fact the number of men will not be half as many as would require for the factories act. The industry would almost be a Home Industry under the supervision of the physician himself. It can be compared to the manufacture of Ayurvedic medicines, most of whose recipes are made by doctors themselves.

(4) Homeopathy being a single drug system is free from all manufacturing complexities involved in its manufacture. Even here there are no specified drugs and there is no limit to the number of them. Any ordinary vegetable plant or every-day eatable can be potentised and used by the physician as necessity arises. Some of the Ayurvedic and Allopathic medicines are now being potentised and put into homeopathic form in which no chemical examination can trade out the drug. Under these circumstances, I am in agreement with the first finding of the sub-committee "That the quality of Homeopathic medicines should not be controlled under the drugs rules".

(5) Coming to the question of licencing the Sales depots and manufacturing concerns of Homeo medicines, I do not see why they should be licenced at all. There would be no meaning in licencing an industry, the products of which cannot be subjected to analysis. This difficulty is recognised by the sub-committee in their statement "That the drugs are greatly diluted before use, sometimes to such an extent that the active principle cannot be detected chemically". I am therefore of opinion that it is extremely inadvisable to subject them to licencing. Another most important reason why they should not be licenced is that the industry is neither big enough to be called an industry, nor its profits strong enough to bear a licence fee. The imposition of such a burden would simply nip the industry in its infancy. The petty sales depots which distribute Homeo medicines to-day in this province are mostly single man's private businesses and are yielding extremely meagre profits. Any licence fee over them would simply make the owners thereof drop their businesses like hot potatoes. As a result the little supplies that the Homeo physicians are now able to get would disappear and they will have to indent for their requirements either to America or to Calcutta. So I would request the Government to strongly protest against the proposed licencing of Homeopathic sales and manufactories.

(6) The third recommendation of the sub-committee that the Homeopathic medicines must be labelled as such, is a harmless one, and at the same time useful to distinguish them from the [illegible] medicines prepared in [illegible]

(7) Finally I beg to submit that Homeopathy is an all comprehensive system, embracing several schools of medicines in their Sukshma form. Its intrinsic potential value is just begun to be recognised by the world at large.

I request the Hon'ble minister of public health to safeguard its interests from the proposals of licencing and afford all facilities for its advancement.

Copy of Bombay Government letter No. 4121/33-H, dated the 19th September, 1946, to the Secretary to the Government of India, Department of Health.

Drugs Rules, 1945.

Extension of the provisions of—to control Homeopathic Medicines.

With reference to your letter No. F. 18-3/46-D, dated the 12th June, 1946, on the subject mentioned above, I am directed to inform you that the Government of Bombay agrees with the recommendations of the sub-committee appointed by the Drugs Technical Advisory Board. Homeopathic medicines usually contain a very small amount of the active drug because they are so highly diluted. It is necessary to specify the desired percentage for different persons to safeguard against mistakes in dilution. It should, therefore, be laid down that if a homeopathic medicine contains or is made from a drug mentioned in the Schedule E (poisons) of the Drugs Rules, the medicine should be certified.

"Contains less than.....per cent. of....."

Copy of Bengal Government letter No. Medl. 2D-5/45(*a*), dated the 21st September, 1946, to the Deputy Secretary to the Government of India, Department of Health, New Delhi.

With reference to the correspondence resting with your letter No. F. 18-3/46-D, dated the 12th June, 1946, I am directed to forward herewith a copy of letter, dated the 7th August, 1946, from the Registrar, General Council and State Faculty of Homeopathic Medicine, Bengal incorporating the resolution passed by the Pharmacy Sub-Committee of the Council at its meeting held on 17th July, 1946, and to say that the functions of the Council relate not only to the control of the profession of homeopathy but also to the registration and control of homeopathic pharmacies and homeopathic charitable institutions and as such the Council may be said to be concerned with matters relating to the import, manufacture, sale and storage of homeopathic drugs. I am accordingly to request that the desirability of consulting the Homeopathic Council and Faculty, Bengal, in matters relating to the control of homeopathic drugs in Bengal may kindly be impressed upon the Drugs Technical Advisory Board.

Copy of letter, dated the 7th August, 1946, from the General Council and State Faculty of Homeopathic Medicine, Bengal, to the Secretary to the Government of Bengal, Department of Health and Local Self-Government.

I have the honour to invite your attention to a copy of letter No. F. 18-3/46-D, dated 12-6-46 from the Deputy Secretary to the Government of India, Department of Health, forwarded to this office by the Deputy Secretary of your Department by Memo. No. Medl. 2D-5-45(*a*), dated 3-7-46 and to state that the Pharmacy Sub-Committee of the above Council has considered the above letter and is of opinion that the Drugs Technical Advisory Board is not correct in its decision, *viz.* "the functions of the Faculty relate only to the control of the profession of Homeopathy, and not to the manufacture, sale and storage of Homeopathic medicines, the Faculty need not be consulted on the subject". In this connection the Pharmacy Sub-Committee draws your attention to section 10 (*e*) of the Statute promulgated under Government Resolution No. 1568 Medl., dated the 24th June, 1941, and to the letter of the Deputy Secretary of your Department No. Medl. 2D-5/45(*a*), dated 10.4.46 to Dr. U. P. Basu, a member of the Drugs Technical Advisory Board, clearly defining the functions of this Council. I am to enclose the following resolution passed by the Sub-Committee at its meeting held on 17.7.46 for your information and necessary action.

Resolution.

" Resolved that unless a Homeopathic physician and a pharmacist conversant with the preparation, sale, uses, etc., of Homeopathic Drugs in accordance with the Homeopathic system of medicine and Pharmacopoeia are included in the Sub-Committee formed by the Drugs Technical Advisory Board, to control Homeo Pharmacies, etc., considerable difficulty will be experienced by the Homeopathic profession as a whole."

With reference to the recommendations of the Sub-Committee of the Drugs Technical Advisory Board, dated 27/1/45 forwarded by the Deputy Secretary of your Department by his letter No. Medl. 1R-18/46, dated 18/7/46, the Pharmacy Sub-Committee after considering the above recommendations, has passed the following resolutions and I am to request you, that if there be no objection, the enclosed resolution may be forwarded to Deputy Secretary to the Government of India, Department of Health.

Resolution.

" Resolved that the label "Homeopathic Medicine" may be affixed only on phials containing mother tinctures (original undiluted drugs), but such labels should not be fixed on diluted and potantised drugs as it involves unnecessary labour and expenses, besides want of space specially in cases, where the medicines are dispensed even in quarter drahm phials."

Copy of letter No. A/588/V-667/46, dated the 7th January, 1947, from the Secretary to Goverment, United Provinces, to the Secretary to the Government of India, Department of Health, New Delhi.

Control of Homeopathic Medicines under the Drugs Rules, 1945.

With reference to Mr. Prem Krishen's letter No. F. 18-3/46-D, dated June 12, 1946, and subsequent reminders, dated September, 11 and December 12, 1946, I am directed to say that the United Provinces Government have consulted the Inspector General of Civil Hospitals and the Director of Public Health, United Provinces and on the whole agree with the opinion expressed by the sub-committee appointed by the Drugs Technical Advisory Board in connection with the control of manufacture and sale of homeopathic medicines in United Provinces.

2. I am, however, to suggest that (*a*) standardisation should be enforced of all mother tinctures, prepared from Crude Drugs, containing powerful poisonous active principles, as sometimes mother tinctures are also prescribed without diluting sufficiently (*b*) the manufacture of mother tinctures from indigenous Crude drugs at the Indian manufacturing concerns should be controlled, as the yield of active principals is variable at different times of the year.

Copy of letter No. $\frac{25781/HM}{19/168\text{-}III}$, dated the 6th September, 1946, from the Government of North West Frontier Province, to the Deputy Secretary to the Government of India, Department of Health, New Delhi.

Control of Homeopathic Medicines under the Drugs Rules, 1945.

I am directed to refer to your letter No. F. 18-3/46-D, dated the 12th June, 1946, and to express the Provincial Government's inability to make any elaborate comments in the matter. They, however, agree with items (*b*) and (*c*) of paragraph 7 of the report of Sub-Committee and still feel that quality of Homeopathic drugs must be controlled to prevent quack dispensing and cheating, etc., in the interests of the general public.

Copy of Sind Government letter No. 4858-C/46, dated the 12th September, 1946 to the Secretary to the Government of India, Department of Health, New Delhi.

Control of Homeopathic Medicines under the Drugs Rules, 1945.

I am directed to refer to Mr. Prem Krishen's letter No. F.-18-3/46-D, dated the 12th June, 1946, on the subject noted above, and to state that this Government is in general agreement with the recommendations of the Sub-Committee. I am, however, directed to suggest for the consideration of the Government of India that in case homeopathic drugs are capable of being used as adulterants of allopathic drugs and *vice versâ*, the storage, manufacture or preparation of both kinds of drugs at one place may be prohibited.