GOVERNMENT OF INDIA

DEPARTMENT OF HEALTH

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

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AGENDA FOR THE FIRST MEETING OF THE DRUGS TECHNICAL ADVISORY BOARD

I.—Consideration of the Draft Drugs Rules, 1942, and comments made on them by members of the Board.

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II.—MINUTES OF THE FIRST MEETING OF THE DRUGS TECHNICAL ADVISORY BOARD HELD ON THE 2nd AND 3rd NOVEMBER, 1942, IN THE OFFICE OF THE DIRECTOR GENERAL, I.M.S., SECRETARIAT, NEW DELHI.

PRESENT :

1. Lieut. General Sir GORDON JOLLY, K.C.I.E., K.H.P., I.M.S., Director General, I.M.S. (*Chairman*).
2. Major General Sir JOHN TAYLOR, I.M.S., Director, Central Research Institute, Kasauli.
3. Dr. F. C. MINETT, D.Sc., M.R.C.V.S., Director, Imperial Veterinary Research Institute, Mukteswar.
4. Dr. H. B. DUNNICLIFF, C.I.E., Chief Chemist, Central Revenues.
5. Dr. B. B. DIKSHIT, M.B.B.S., D.P.H., M.R.C.P., Ph.D., Haffkine Institute, Bombay.
6. Mr. P. DAS, B.S. (Pharmacy), M.S. (Pharmacy) (Michigan), C/o Stadco Stores & Laboratories, Shillong.
7. Professor BIRES CHANDRA GUHA, Ph.D., D.Sc., (Lond.), Professor of Applied Chemistry, University College of Science, Calcutta.
8. Professor MAHADEV LAL SCHROFF, A. B. (Cornell), M.S. (Mass), Professor of Pharmaceutical Chemistry, Benares Hindu University.
9. Dr. ANIL KUMAR SEN, M.B. (Cal.), Director Laboratories of Boilogical Research, Bengal Chemical & Pharmaceutical Works, Calcutta.
10. Dr. S. RAJAGOPAL NAIDU, B.A., M.B.B.S., M.Sc., F.I.C., D.I.C., Chemical Examiner to Government of Madras.
11. Mr. A. F. MACCULLOCH, M.B.E., M.A., B.Sc., F.I.C., A.M.I., Chem. E., Chief Advisory Chemist to the Director General, I.M.S. (*Secretary*).

I. The Chairman read apologies for absence from Dr. Prasad and Dr. Kutumbiah, both representative of the Medical Council in India.

II. Chairman's remarks—A copy of the Chairman's remarks is attached as Appendix A. The Board decided to send a copy of the Chairman's remarks to Br. Colonel Sir Ram Nath Chopra.

After the Chairman's remarks Dr. A. K. Sen enquired regarding a letter dated the 14th October, 1942 which he had written to the Secretary, Drugs Technical Advisory Board. Dr. Sen stated that in the letter he had given a formal notice for bringing a motion before the Board for the constitution of sub-committees by the Board to scrutinise the Draft Drugs Rules, 1942. He stated that Sir G. S. Lajpai had given an assurance in the Central Legislature on behalf of the Government that this procedure for framing of the Drugs Rules under the Drugs Act would be followed. After some discussion on this question, the Chairman suggested that in order to save time, the Draft Rules may be considered item by item and if in course of discussion, the necessity for appointing sub committees arose, it might be then considered. The Board agreed to this suggestion and proceeded to the consideration of the rules.

III.—CONSIDERATION OF THE DRAFT DRUGS RULES, 1942

PART I

Rule 1 (3)—Some members of the Board were of opinion that in order to ensure uniformity in enforcing these rules throughout British India, that is, in areas administered by the Central and Provincial Governments, the Central Government, before issuing any notification in the official Gazette, as contemplated in Draft Rule I(3), should consult the Drugs consultative Committee as envisaged in the Drugs Act, 1940, Sec. 7 (*i*). In the opinion of some members that Committee should already have been constituted.

Proviso to Rule 1 (3)—It was the opinion of some members of the Board that the Central Government before issuing any notification under this Rule should consult the Drugs Technical Advisory Board.

PART II

Rule 3 (iii)—A considerable amount of discussion took place over rule 3 (*iii*). The Board accepts this function of the Central Drugs Laboratory, but desires to impress on the Central Government the desirability of consulting the Drugs Technical Advisory Board on all technical matters which pertain to the working of the Laboratory.

The Board is strongly of the opinion that ordinary commercial analytical work for firms should not be undertaken by the Central Drugs Laboratory.

Rule 7.—The Board agrees to the publication of the Schedule of Fees in Schedule B, but wishes to point out that it will probably require revision in detail in the light of criticism received after publication of the Drugs Rules for objections.

PART III

Rule 9.—A considerable discussion took place over patent and proprietary medicines in the indigenous systems of medicines which contain drugs used in the Allopathic system of medicine. Members were apprehensive lest the indigenous systems of medicines would be used as a means of evading control. The Board would like to be assured by Government that any medicines of the indigenous systems which contain Allopathic drugs would be subject to control.

Rule 12 (i).—In line 3 change ' and ' to ' or '.

Rule 15 & 16.—No provision is made for with-holding the registration of patent and proprietary medicines of no therapeutic value. The Board is anxious that there should be a full disclosure of the composition of patent and proprietary medicines on the label of containers of such medicines on the same lines as section 11 of the Pharmacy and Medicines Act, 1941, of Great Britain. it was considered doubtful if any rule enforcing the full disclosure of the composition of medicines can be made under the Drugs Act, 1940. If it is possible the Board urges on Government the insertion of a rule to this effect. The evil results of the class of medicines known as " Secret Remedies " are well known and their eradication from India would be a very useful step in the control of the drug trade.

It was pointed out that an applicant for the registration of a patent or proprietary medicine had by paragraph 2 of Form 3 to send in copies of the labels and wrappers intended to be used. A sentence is recommended in line 4 of Rule 15 after the word ' medicine ' as follows :—

" Or if the labels and wrappers do not confirm to the Drugs Rules ".

Rule 18.—The Board notes that the fee of Rs. 10/- is nominal and quite insufficient to cover the cost of test.

PART IV

Rule 21 (b).—The Board suggests that the Central Government should specify in the rules the official who will perform the duties of licencing authority.

Rules 23—25.—The Board suggests that the rules for an import licence should be on the same lines as sections 23 and 24 of the Therapeutic Substances Regulations of Great Britain, 1931, including the form of import licence. In particular there should be only one agent in India for the import of any one manufacturer of items under Schedule C. The Board is strongly of opinion that much more rigorous control would be exercised over items in Schedule C by having ' a sole agent ' in India for a manufacturer abroad. The Board is also of opinion that the right to inspect manufacturing premises abroad should be included in the rules and that the rules on this matter should be the same as for firms in India manufacturing these items.

Rule 28.—The Board recommends that there should be an appeal to the High Court as is the case with manufacturers in the U. K. and that the proviso to Sections 2 (4) of the Therapeutic Substances Act, 1925, should be added to this rule. The Board considered that this was a reasonable concession to the licensee.

Rule 29.—A considerable discussion took place over the import of drugs specified in Schedule C or C (1) which were approaching the date on their label beyond which they should not be used. Members were apprehensive that if no time limit was inserted, some consignments of drugs under this Schedule might be imported which were near the expiry date. It was pointed out that drugs under this schedule are manufactured by reputable firms with such a potency that they are still at or about their reputed strength at their expiry date, and consequently have a very high potency even at the date on which it is stated that they should no longer be used. It was decided not to alter this rule.

Rules 32-33.—The Board notes that there are some differences between Draft rule 32 and the rules for a research licence in the U. K. as stated in Section 25 of the Therapeutic Substances Regulations, 1931. They recommend that the latter should be used as a model for amending Rule 32.

The following alterations to draft rule 32 and to Form 9 will result :—

Add at end of paragraph (*b*) " Or in such other places as the licensing authority may from time to time authorise ".

Insert the word ' prior ' before the word ' notice ', in line 2, paragraph (*c*).

Insert the word ' and ' before ' to inspect ' in line 3, paragraph (*c*).

Replace ' to ' by ' and ' in line 4 of paragraph (*c*).

Replace ' four ' by ' one ' in paragraph (*c*).

Form (*9*).— *Insert* after ' shall ' in line 1 of paragraph 3 ' unless previously suspended or revoked '.

Insert in line 4 of paragraph 1, ' or in such other place as the licensing authority may from time to time authorize. '

Rule 35 (*iii*).— *Insert* the words ' average British or United States Pharmacopoeial ' between the figure ' 100 ' and the word ' doses' for the reason that in the B. P. or U.S.P. the dose varies within wide limits. In the proviso *insert* ' in an exceptional case ' after ' may '.

Rule 38 (*ii*).— Delete the phrase ' or in the alternative....standard ' in line 5– 7, as it is redundant.

Rule 40 (*2*).— The Board considers that any alteration authorised by the Customs Collectors must be carried out under the supervision of a Customs official before the drug is released for sale and that this should be stated in the rule.

The Board notes that no rule has been drafted prescribing the places at which drugs may be imported and prohibiting their import at any other place according to Section 12 (2) (*f*) of the Drugs Act.

PART V

Rule 43.— The Board recommends the insertion of the following qualifications in place of the draft qualifications of Government Analysts :—

A person who is appointed a Government Analyst under the Act shall be a person who :—

(*a*) is a graduate in medicine or chemistry of a university recognised for this purpose by the appointing authority and has had not less than three years post graduate experience in the analysis of drugs in a laboratory under the control of :—

(*i*) a Government Analyst appointed under the Act,
(*ii*) a Chemical Examiner to Government, or
(*iii*) a fellow of the Institute of Chemistry of Great Britain (Branch E).

or

(*b*) has a first or second class degree in Pharmaceutical Chemistry or Pharmacy, or a post-graduate degree in Chemistry with Pharmaceutics as a special subject from a university recognised for the purpose by the appointing authority and has had not less than two years post-graduate experience in the analysis of drugs in a laboratory under the control of :—

(*i*) a Govt. Analyst appointed under the act,
(*ii*) a Chemical Examiner to Government, or
(*iii*) a Fellow of the Institute of Chemistry of Great Britain (Branch E).

or

(*c*) is a Fellow of the Institute of Chemistry of Great Britain (Branch E).

Provided that for the purpose of the examination of items in Schedule C the person appointed shall be a graduate in medicine of a University recognised for the purpose by the appointing authority who has had not less than 3 years experience of testing biological products in items of Schedule C in an institution approved by Government.

Provided that for a period of four years from the date on which Chapter IV of the Act takes effect in the Province persons whose qualifications, training and experience are regarded by the appointing authority as affording, subject to such further training, if any, as may be considered necessary a reasonable guarantee of adequate knowledge and competence may be appointed as Government Analysts.

Provided further that no person shall be appointed for any area who is engaged directly or indirectly in any trade or business connected with the sale of drugs in that area.

The appointment of a Government Analyst and the terms of his appointment and removal from his post shall require the approval of Government.

Rule 44.— Insertion of Rule 44 (*ii*) as follows is recommended :—

" A Government Analyst will from time to time forward to Government bulletins giving the result of analytical work and research for publication at the discretion of Government for the use of the drug trade ".

Rule 48 (*a*).— In line 1 after ' Pharmaceutical Chemistry ' *Insert* the words " or post-graduate degree in Chemistry with Pharmaceutics as a special subject ".

Alter the first proviso to read as follows :—

" Provided that only those inspectors who have had not less than three years experience in the manufacture and testing of substances specified in Schedule C in a laboratory approved for this purpose by the licensing authority, shall be authorised to inspect the manufacture of items mentioned in Schedule C ".

In the third proviso, in line 3, after the word ' department ' insert " who is a registered medical practitioner or a graduate in science ".

Rule 49.— In line 2 *delete* " Chief Administrative Officer of the Province " and insert " Provincial Government ". The Board felt this should be done in order not to restrict choice to this official.

Rule 52 (*2*).—Line 2 after the word " inspect " *insert* ' not less than twice a year '. In line 3 *delete* ' investigate fully ' and ' in actual operation '. The latter deletion is proposed to prevent unnecessary disclosure of trade secrets for carrying out a manufacturing process. Only general methods of manufacture require to be revealed as a rule.

PART VI

Rule 59.—This Rule should read ' Licensing Authority means the authority appointed by Govt. to perform the duties of the licensing authority under these rules '.

In line 3 *insert* ' Govt. ' for Chief Administrative Medical Officer '.

The reason for this recommendation is to bring it into line with Rule 21 (*b*).

In Form 17, 2 (4) delete ' cold ' in line 1.

Rule 63.—In line 5 replace ' adequate ' by ' proper '.

Rule 64.—Delete ' and ' in line 2 of sub-section (4) (e) and add after ' no. ' the words ' and if the drug is post-dated according to section 105 of these Rules '. The Board recommends that a record be kept of sales under Section 105.

In Rule 64 (11) add ' Pharmaceutical Chemist ' after ' dispensary ' in line 4.

In Rule 64 (11) Explanation (a), insert after ' Chemistry ' the words ' of an institution approved by the licensing authority.'

In Rule 64-A(2) line 2, alter ' Central Govt. ' to ' a High Court of Judicature ' as High Court is the authority of appeal indicated in the United Kingdom by the proviso to Section 2(4) of the Therapeutic Substances Act of Great Britain, 1925, for manufacturers of items specified under Schedule C.

The Board recommends the insertion of the 4th Schedule to the Poisons Rules, 1935, of Great Britain. This will result in the addition of the following Rules at 64 (8 to 10).

Rule 64 (8).—Substances specified in Schedule H shall not be sold by retail except on and in accordance with the prescription of a registered medical practitioner.

Provided that no prescription shall be required for sale or supply to a registered medical practitioner, hospital, infirmary or an institution approved by an order of the Licensing Authority.

Rule 64 (9).– For the purposes of Rule 64 (9) a prescription shall :–

(*a*) be in writing and be signed by the person giving it with his usual signature and be dated by him ;

(*b*) specify the name and address of the person for whose treatment it is given ;

(*c*) indicate the total amount of the medicine to be supplied and the dose to be taken.

Rule 64 (10).– The person dispensing the prescription shall comply with the following requirements :–

(*a*) the prescription must not be dispensed more than once unless the prescriber has stated thereon that it may be dispensed more than once ;

(*b*) if the prescription contains a direction that it may be dispensed a stated number of times or at stated intervals, it must not be dispensed otherwise than in accordance with the direction ;

(*c*) at the time of dispensing there must be noted on the prescription above the signature of the prescriber the name and address of the seller and the date on which the prescription is dispensed.

PART VII

Rule 66.– Line 4, in place of ' chief medical officer of a province ' *insert* ' licensing authority appointed by the Provincial Government '.

Rule 68 (2).– In place of (1) and (2), *Insert* the following :–

(1) a graduate in Pharmacy or Pharmaceutical Chemistry of a university recognised by the licensing authority,

(2) a graduate in science who for the purposes of his degree had studied chemistry as a principal subject and has had at least two years practical experience in the manufacture of drugs, or

(3) a person whose general training, knowledge of chemistry and practical experience, extending over not less than three years, in the manufacture of drugs are in the opinion of the licensing authority adequate.

Rule 72.– The inspection fee of Rs. 30 is considered to very inadequate. The Board strongly recommends raising it to Rs. 100. It probably will take an inspecting officer a week to carry out an inspection of a premises licensed to manufacture drugs specified in Schedule C.

Rule 76.– Line 6, replace ' investigate ' by ' inspect '.

Rule 81-A(b).– *Insert* ' High Court ' for ' Central Government ' as High Court is the authority for appeal in the case of manufacturers under Section 2 (4) of the Therapeutic Substances Act of Great Britain 1925.

PART VIII

Rule 84.– Line 2, ' is sold '. It is not clear to the Board why regulations for the sale of drugs manufactured for examination tests and analysis are necessary. The Board considers that the Drugs are manufactured for the purposes of research only as explained in Rule 88-A.

The use of the word ' investigate ' in line 4 of Rule 88(*b*) would seem to indicate that the drugs manufactured under this licence cannot be sold.

Rule 86.– Alter ' Chief Medical Officer of the Province ' to ' Licensing Authority '.

Rule 88-A(b).—*Insert* ' High Court ' for ' Central Government ' as High Court is the authority for appeal in the case of manufacturers under Section 2(4) of the Therapeutic Substances Act of Great Britain 1925.

PART IX

Alter the heading to ' Labelling, Packing and Advertisements '.

Rule 91.– In lines 1 and 2 of the proviso, alter ' ampoule ' to ' capsules and cachets ', as it is considered that all ampoules of Schedule C items, as stated in Rule 104 should be individually labelled, but such items of C (1) drugs or other drugs in the form of cachets, capsules, tablets, etc., should not be individually labelled.

Rule 92.– *Delete* ' for internal use ' in line 1, as para. 2 deals with medicines for external application.

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Rule 98.—It is understood from section 43 of the memo. that all patent and proprietary medicines have to be registered at the Central Drugs Laboratory whether they have the formula printed on the label or not. The Board has some doubt whether this decision has the authority of the Act behind it, as from Section 10 (*d*) of the Drugs Act one could infer that only patent and proprietary medicines which have no formula on the label have to be registered at Central Drugs Laboratory.

Rule 101.—This rule may be reconstructed as follows :—

> ' Diseases which a drug may not purport to cure '. No drug whi h by means of any statement, design or device accompanying it, or issue, or displayed in connection with it, or by any other means purports or claims to cure any disease or ailment specified in Schedule 1, or to procure, or assist to procure the miscarriage of women, may be sold, stocked or exhibited for sale.

The latter part is taken from Section 9 of the Pharmacy and Medicines Act 1941 of Great Britain.

PART X

Rule 105.—Line 2, *delete* 'or stock' as the prohibition is of sale of substance after prescribed date.

Rule 109(h).—*Add* ' except preparations which, after being sealed in the containers, have been sterilised by heat in a manner satisfactory to the licensing authority ' to bring it into agreement with (*g*).

Rule 111 (*a*).—Page 28, line 2—Printer's error. *Insert* ' t ' before ' he '.

Rule 112.—*Add* as second paragraph to Rule 112 (1) :—

> " When an antiseptic other than a phenolic antiseptic is used the dilution to be employed shall be that approved by the Licensing Authority. "

The Board recommends the insertion of this sub-section as non-phenolic antiseptic such as phenyl mercuric nitrate are now used.

Rule 116.—*Insert* the lines 9 and 14 *after* ' symptoms ' ' within 7 days '.

On page 34, Form 4, Rule 7 is an error for Rule 9.

Rule 42.—In Form 18, *add* as item 4 of conditions of licence :—

> ' No drug in Schedule C(1) shall be sold unless the precautions necessary for preserving the properties of the contents have been observed throughout the period during which it has been in the possession of the licensee '.

The Board considers that conditions of storage are the most essential factor in the Control of Schedule C(1) drugs.

Schedule C.

After Part X in Line 1 *add* ' and Schedule F '.

Schedule C (1).

After 73 in line 2 *add* ' and Part IX of Schedule F. '

In para. 4 *delete* ' and other vitamin preparations '.

Add :—

5. Preparations containing any vitamins in a form not to be administered parenterally.

6. Preparations containing liver extract in a form not to be administered parenterally.

Preparations containing hormones in a form not to be administered parenterally.

Page 54.—Line 27, the word ' pomegrarate ' is misspelt.

Page 57.—*Delete* Sulphonal ; alkyl sulphonals from Part 2 of list of Poisons, Rearrange Part 2 into correct alphabetical order. *Delete* the item ' Sulphanilamide etc. ' and enter the following as a separate item on page 56 after Oxycinchoninic Acid. ' Paraaminobenzenesulphonamide ; its salts, derivatives of para-aminobenzenesulphonamide having any of the hydrogen atoms of the para-amino group or of the sulphonamide group substituted by another redical their salts. '

Page 60, Schedule F. Part 1(B), 4(3).—In line 2 the Board agrees to delete the words ' unless the licensing authority grants exemption from this provision '. The Board is influenced in this decision by the fact that the animal may be suffering from some disease which may not be diagnosed until the animal is killed. The Board realises that this deletion may cause considerable difficulty and additional expense to institutions manufacturing this vaccine lymph but at the same time they would be grateful if the Central Government would urge Provincial Governments to accept the deletion.

Page 63, Schedule F. Part 1(D), 4(2).—Line 6, printer's error, ' arrual ' should be ' animal '.

The Board suggests that the provisions regarding Part II (E) Tetanus' Toxoid should be entered at the end of Part 1 of Schedule F.

The Board recommends that gas-gangrene antitoxins in Part IV should be placed together in this section, that is that the sections dealing with sedemations, Vibrion Septique and Histolyticus on pages 85 to 89 should follow immediately after Perfringens on page 80 and precede the section on Anti-neumococcus. The letter heading each section may be changed accordingly.

Page 85, Part IV (1) 3(2).—In line 5, *delete* the following :—

> ' A solution of the separated antitoxic globulins shall not contain more than 10% of solid matter '.

At the end of Part IV on page 89 *add* ' Provisions applicable to Antivenom Serum (Antivenene). A copy of the provisions is attached as Appendix B.

The Board suggests inclusion of tests for this serum as it is largely made in India.

Page 89, Part V, line 1.—*Insert* ' Neo ' before ' Salvarsan '.

Page 97.—The Board recommends that Parts IX; X and XI should be amalgamated into one Part IX, having letters.

A Digitalis group of drugs and Ergot and its Derivatives.

B Fish Liver Oil.

C Liquor Adrenalinae Hydrochloridi.

'And vitamin preparations' should be deleted from line 1 of the present Part X as this item has now a separate section.

Under the heading Part IX *insert* 'All substances specified in Schedule C(1) shall be stored in a cool place and away from light'.

Page 97, 98 and 99.—Liquor Adrenalinae Hydrochloridi mis-spelt. It should be corrected.

Pages 99.—In line 12 *delete* 'The permissible limit of error is ± 10'. It was considered that this was a matter for the consideration of the Central Drugs Laboratory.

Containers—The sentence should read as follows :—

'The container shall be made of non-alkaline, amber coloured resistance glass'.

At the end of Part IX *insert* :—

(D) Preparations containing any vitamins in a form not to be administered parenterally.

Tests.

Drugs containing vitamins shall be submitted to the tests prescribed in the British Pharmacopoeia or the United States Pharmacopoeia.

(E) Preparations containing liver extract in any form not to be administered parenterally.

Tests.

Drugs containing liver extract shall be submitted to the tests prescribed in the British Pharmacopoeia or the United States Pharmacopoeia.

(F) Preparations containing hormones in any form not to be administered parenterally.

Tests.

Drugs containing hormones shall be submitted to the tests prescribed by the Licensing Authority.

Page 100.—The Board recommends that the fourth schedule of poisons in the Pharmacy and Poisons Act of 1933 of Great Britain be inserted as Schedule H re-lettering the later schedules accordingly. An up-to-date copy of the Schedule is attached as Appendix C.

Schedule I may be divided into two sections as follows :—

SECTION A.

Blindness	Diabetes
Bright's disease	Epilepsy
Cancer	Fits
Cataract	Goitre
Delayed Menstruation	Heart Diseases

High Blood Pressure	Paralysis
Infantile Paralysis	Rupture
Leprosy	Sexual Impotence
Leucoderma	Small Pox
Lockjaw	Trachoma
Locomotor Ataxia	Tuberculosis
Obesity	Tumours.

SECTION B.

The following diseases and ailments using the nomenclature as a general expressions :—

Female Diseases	Fevers	Venereal Diseases.

Page 103—Alter 117 in Rule 117 to 118.

Section 5 (Class of Drugs).—It was recommended that the following draft should replace the existing draft.

Drugs supplied by a registered medical practitioner to his own patient or drugs in schedule C supplied by a registered medical practitioner at the request of another such practitioner if it is specially prepared with reference to the condition and for the use of an individual patient provided the registered medical practitioner is not (*a*) keeping an open shop or (*b*) selling across the counter or (*c*) engaged in the importation, manufacture, distribution or sale of drugs in British India to a degree which renders him liable to the provisions of Chapter IV of the Act and rules thereunder or drugs supplied by a hospital or dispensary maintained or supported by Government or a local body or by charity or voluntary subscription.

IV. In accordance with Section 5(4) of the Drugs Act, the Board recommends that 7 members including the Chairman and Secretary should constitute a quorum for meetings. Either the Chairman or the Secretary must be present at a meeting of the Board.

V. The Board recommends the addition of the United States Pharmacopoeia to the standards for 'other drugs' in the Schedule to the Drugs Act, 1940, and as 'another Pharmacopoeia' to be added to Section 3(*d*) of the Drugs Act, 1940. *Add* 'of the United States Pharmacopoeia' in line 2 of Part XII of Schedule F of the Drugs Rules.

VI. The Board urges Government to constitute the Central Drugs Laboratory at the earliest possible date so that it be in a position to begin the work which it is called upon to do under the Drugs Act, 1940.

It was agreed that a statement showing the existing organisation and the proposed organisation of the Central Drugs Laboratory may be circulated to members of the Board.

VII. The Board suggests the early information of a central library of literature pertaining to the regulation of the sale and manufacture of drugs in other countries.

VIII. The Board recommends strongly that legislation should be proceeded with by Government at an early date for the control of Pharmacy in India. Members point to the fact that the United Kingdom, despite the War, proceeded with passing, in 1941, a very controversial piece of drug legislation in the Pharmacy and Medicines Act, 1941.

APPENDIX A.

Chairman's remarks.

Gentlemen, in welcoming you today to this the first meeting of the Drugs Technical Advisory Board, I would like to refer back to the Report of the Drugs Enquiry Committee presided over by my distinguished colleague and old friend Colonel Sir Ram Nath Chopra who, as the leading Pharmacologist of this country, has done more than any other man towards the formation of a sound scientific and ethical basis on which to build the drug industry of India. The report of the Chopra Committee was itself a powerful factory in preparing Government, the Legislature and the public for the introduction of the Drugs Act and the establishment of this Board, and I am sure you will all join with me in acknowledging the debt which India owes to Sir Ram Nath Chopra and our satisfaction that he is still actively engaged in the task to do investigation and research in the field of drugs which he has made his life study.

I would also like to pay tribute to those leading drug manufacturers of India who, like the great international houses, have refused to listen to invidious suggestions for the lowering of standards or to countenance the production and sale of low-grade pharmaceuticals.

Following the report of the Drugs Enquiry Committee in 1931, a long period of incubation ensued before the hatching out in 1940 of the bill " to regulate the import, manufacture, distribution and sale of drugs " which passed into law as the Drugs Act, 1940. Unfortunately, the implementing of most of the recommendations of the Drugs Enquiry Committee has taken place in an abnormal period when all other considerations have had to give way to measures essential for the prosecution of the war, and for this reason there has been considerable delay which could otherwise have been avoided. You will be aware, however, that as far back as 1936 the Government of India, without waiting for legislation, proceeded with the formation of a nucleus of the Central Laboratory recommended in the Chopra Report, which they called the Biochemical Standardisation Laboratory and which was established in Calcutta under the Directorship first of Colonel Chopra and latterly of his pupil Dr. B. Mukerjee. This laboratory has been of the greatest value in carrying out much necessary work preliminary to the establishment of the Central Drugs Control Laboratory which is a primary injuction of the Act. I may add that the Biochemical Standardisation Laboratory has participated in the war effort by undertaking the testing of drugs and other medical preparations required by the Army.

Another principal direction of the Act is the formation of the Drugs Technical Advisory Board. You will note that the object of our Board is " to advise the Central Government and the Provincial Governments on technical matters arising out of the administration of the Act and to carry out the other functions assigned to it by the Act. " Government have felt that a necessary preliminary to the administration of the Act is the formulation of rules laying down the functions of the Central Drugs Laboratory and the various procedures and prescriptions required under sections 6, 12 and 33 of the Act. I hope that, when these Rules have been agreed upon, the Central Drugs Control Laboratory will come into being. It is the duty of Government under the Act to make these rules. Government have drafted them and, as prescribed by the Act, have called us in consultation to consider them. Their letter reads as follows :—

> " I am directed to forward 30 copies of the draft Rules under the Drugs Act, 1940 (XXIII of 1940) and of a memorandum on the draft rules and to request that a copy of the draft rules and memorandum may be supplied to each member of the Drugs Technical Advisory Board and that it may be ascertained whether the Board has any suggestions to make for modification of the draft rules before they are published for objection. The reasons for any modification which the Board may suggest should be briefly stated.
>
> 2. I am to invite attention to paragraph 3 of the memorandum and to request that the views of the Board may be obtained on the question what other pharmacopoeia in addition to the British Pharmacopoeia should be prescribed

> for the purposes of standards of indentity, purity and strength of drugs other than sera, vaccines, vitamins and similar products. In this connection I am to say that it has been suggested that the standards of all authoritative pharmacopoeias should be recognised subject to the condition that when the standard differs from that laid down in the British Pharmacopoeia the name of the pharmacopoeia shall be clearly stated on the label of the container ".

You will observe that our advice is sought on two points, first on the draft rules and secondly as to which pharmacopoeias in addition to the British ones, it is desirable to include in the schedule to the Act. The draft rules have been circulated to you all for comment and the comments have also been circulated. A point I should like to emphasise is the need to obtain a set of rules which will be acceptable not only to the Government of India but to the Provincial Governments on whom rests the responsibility for administering the Act within their boundaries. It is, therefore, hoped that these draft rules, amended where necessary on our advice, will be accepted as a model by Local Governments and adopted by them.

APPENDIX B.

Provisions applicable to Antivenom Serum (Antivenene).

Definition and Proper Name.

1. Antivenom Serum (or antivenene) is the serum or the globulins containing the specific neutralising substances separated from the blood of animals which have been immunized against the venom of one or more poisonous snakes. The proper name of the substance is Antivenom Serum (or antivenene) followed by names of the species of snake or snakes against the venom or venoms of which it has been prepared.

Standard preparations.

2. The standard preparations are quantities of the dried venom of the Indian Cobra (Naia tripudians).

Russell's viper (Vipera russelli).

Kept at the Central Research Institute, Kasauli.

Quality.

3 (1) Antivenom serum (or anivenene) shall be issued for therapeutic use in the form of either—

(*a*) the serum separated from the blood or plasma of immunized animals ; or

(*b*) the solution of the globulins containing the specific neutralizing substances ; or

(*c*) a dry powder prepared from (*i*) the natural serum or (*ii*) the globulins containing the specific neutralizing substances.

(2) If issued in fluid form the liquid shall, at the time of issue, be clear or show, at most, a very slight opalescence or precipitate. Preparations of the natural serum (the liquid production of decantation of the coagulated blood without any addition, other than antiseptic, or subtraction) shall not contain more than 10 per cent. of total solid matter. A solution of the separated neutralizing globulins shall not contain more than 20 per cent. of total solid matter.

Strength.

4 (1) The potency of antivenom serum (or antivenene) shall be determined in accordance with a method approved by the licensing authority.

Labelling.

5 (1) The label on the container shall indicate :—

(*a*) the potency of the preparation expressed as the weight of dried venom of each species of poisonous snake against which it is prepared, which is neutralized, under the method of test employed, by one cubic centimetre of the serum,

(*b*) the total number of cubic centimetres in the container.

(2) The label on the container or the label or wrapper on the package shall indicate the nature of the particular product, that is to say, whether natural serum, or a solution of the globulins containing the specific neutralizing substances, or a dried natural serum or dried globulins.

APPENDIX C.

Schedule H.

Substances required to be sold by retail only upon a prescription given by a registered medical practitioner.

Amidopyrine ; its salts.

Barbituric acid ; its salts ; derivatives of barbituric acid ; their salts ; compounds of barbituric acid, its salts, its derivatives, their salts, with any other substance.

Dinitrocresols ; dinitronaphthols ; dinitrophenols ; dinitrothymols.

Para-aminobenzenesulphonamide ; its salts ; derivatives of para-aminovenzenesulphonamide having any of the hydrogen atoms of the para-amino group or of the sulphonamide group substitute by another radical ; their salts.

Phenylcinchoninic acid ; salicyl-cinchoninic acid ; their salts, their esters.

Sulphonal ; alkyl sulphonals.

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Chairman, Drugs Technical Advisory Board.
14-3-44.

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