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Government of India

Ministry of Health and Family Welfare

Minutes of the Drug Consultative Committee Meetings

(From XII to XVIII Meetings)

Central Drug Standard Control Organisation
Directorate General of Health services
New Delhi

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PART II

MINUTES OF THE SIXTEENTH MEETING OF THE DRUGS CONSULTATIVE COMMITTEE HELD AT NEW DELHI ON THE 28TH AND 29TH NOVEMBER, 1972.

Welcoming the members the Chairman stated that although the Drugs Consultative Committee generally meets once a year, the provocation for this rather speedy meeting (the second one within a period of 12 months) was the "Pipmol" incident in Tamil Nadu. The Pipmol incident, he said, had shaken the confidence of the medical profession in the quality of drugs manufactured by Indian firms that is to say 100% Indian firms as distinct from foreign subsidiaries in this country. In particular, the products of the small-scale sector of the drug industry have become suspect in quality. Three measures, the Chairman added, would deserve the consideration of the members, namely :-

a. Manufacturers must be made to test all raw materials used in drug manufacture.

b. the complete composition of each preparation which covers particulars of active ingredients, with those of excipients, solvents, flavouring and colouring agents etc. must be made available to the licensing authority by the manufacturers, and,

c. Measures necessary for tightening of the tests carried out by the "Approved Laboratories" and the procedure to be followed for sampling in such cases need to be discussed and settled.

Advertising to inspection of the Pharmaceutical services and the Stores Organisation in hospitals, the Chairman said that the experience of the Central Drugs Control Organisation indicates that if sustained efforts in this direction are kept up, the quality of hospital services can be improved

substantially. He appeals to the Drugs Control authorities of the Punjab, Haryana, U.P., Bihar, Rajasthan, West Bengal, Orissa, Assam, Andhra Pradesh and Madhya Pradesh to pay greater attention to inspections of hospitals. Similarly, he suggested that inspection of firms on which orders are placed by the D.G.S. & D. should be done jointly by the States and Central Drugs Control Organisation.

Re-ferring to the "Intensified Drugs Sampling Programme" initiated by the Central Drugs Laboratory, the Chairman informed the Committee that a fairly good measure of success had been achieved in assessing the quality of our essential drugs, namely, Cyanocobalamin, Vitamin B_1, Vitamin C and Chloramphonicol. The Central Drugs Laboratory, he said, would be embarking very soon on the next phase of the programme covering a new category of drugs.

Adverting to the subject of sampling of drugs, Chairman suggested that the Drugs Control at the Centre and in the States should concentrate its attention on commonly-used items such as Aspirin tablets, APC tablets, Ferrous sulphate tablets, Gripe Water, Calcium with Vit. D_2, Eye drops and intments, anti-T.B. drugs, Prednisolone tablets etc. as there was reason to doubt the quality of these preparations. If possible, it would be best if samples could be picked up from smaller towns and rural areas.

Considering the increased incidence of sub-therapeutic formulations, he advised to states to scrutinize carefully the applications received by them for manufacture of drug formulations so as to weed away sub-therapeutic or irrational combinations. He pointed out that the number of manufacturers of semi synthetic Penicillins, newer tranquilisers such as diazepam, etc. is steadily on the increase and that since the pharmacopoeial specifications of these drugs are difficult to conform to, the capabilities of the applicant firms to comply with the pharmacopoeial standards must be clearly established before they are licensed to manufacture these formulations.

Talking about the collection of date on the activities of the small scale units, the Chairman pointed out that out of 1996 firms, information

regarding 799 firms was available so far and requested the State Drugs Control authorities to take personal interest and expedite the remaining information about such firms. The over-all information would provide meaningful points to the Drug Control Administration about the specific sector of the drug industry which need assistance both in regard to development of quality control consciousness as well as in respect of raw materials, equipment etc.

Turning to the developments in the Central Drugs Control Organisation, the Chairman said that the Central Inspectorate would be strengthened soon and help the States to a greater extent. The training programme of inspectors was going on satisfactorily and the States should avail themselves of this programme. From 1st December, the Chairman stated, the Training programme for Analysts from States would commence at the Central Drugs Laboratory, Calcutta. The training programme in connection with the quality control over sera and vaccines carried out at the Central Research Institute, Kasauli was most instructive and useful. If sufficient number of persons are available for training, another batch could be trained at the Central Research Institute, Kasauli.

The Chairman then acquainted the members with the Plan Schemes which a Task Force constituted by the Planning Commission had recommended for implementation in the Fifty Five Year Plan. Shri M.K. Rangnekar, Commissioner, Food & Drugs Administration, Maharashtra State and Shri P.S. Ramachandran, Drugs Controller (India) were associated with the work of the Task Force. The following broad recommendations of the Task Force were :-

1. The administration of food control and drug contdrol should preferably vest in a single authority,

2. The centre should assist the States by establishing atleast ten combined Food & Drug Laboratories, in States.

3. Centre should extend financial assistance to States for constituting mobile squads complete with Police Personnel, watchers and fitted with wireless equipment for tackling spurious drugs and food adulteration,

4. Centre should assist states for increasing the complement of the Drugs Inspectorate.

These recommendations were under consideration of the Planning Commission. He suggested to the members that they should keep these recommendations in mind and include appropriate schemes in the State sector of the Plan to complement them.

The attention of the Committee was drawn by the Chairman to the increasing incidence of spurious drugs in the country. He told the members that strip-packed tablets resembling closely the most popular brands of drug formulations in the market had been reported from Jammu & Kashmir, Punjab and Haryana. The areas of Meerut and Agra, are reported to abound in spurious drugs. Drugs fakers were also active in Bihar and Madhya Pradesh. Tackling such an unlawful activity, he said, would need the help of plain clothed "Watchers", police assistance etc. and suggested to the members that State Drugs Control Administration should discuss with their respective Police Departments and enlist police help for carrying out raids etc. The Central Govt. could also write to the State Govts. for assisting the Drugs Control Departments with Police personnel etc. in case concrete proposals are made in this regard.

The Chairman said that the problem of spurious drugs was studied by the Task Force constituted by the Planning Commission in all its aspects. The Task Force recommended the setting up of anti-spurious squads in the States and the Centre. According to its recommendation, 50% of the cost in setting up these squads would be borne by the Central Government. The Planning Commission had agreed to the proposal in principle.

As for central assistance for setting up drug testing laboratories in States, Chairman stated that the matter was taken up with the Planning

Commission and the view of the Planning Commission was that states should be helped to set up combined Food & Drugs Laboratories. During the Fifth Plan, ten such laboratories are proposed to be set up and efforts are being made to include this as a centrally sponsored scheme. Advance action on this scheme be continued, was proposed to be taken in the Fourth Plan itself.

Regarding misuse of Psychotropic substances, the Chairman agreed that control over such drugs should be exercised as in the case of narcotic drugs. He informed the members that the report of the sub-committee of the Drugs Consultative Committee for exercising control over the manufacture, sale, distribution etc. of Psychotropic drugs was ready and that this report would be circulated to the members soon. At Chairman's request Dr. Gothoskar Dy.Drugs Controller (India) and Member-Secretary of the sub-committee apprised the members of the salient recommendations contained in the sub-committee's report.

A separate schedule covering Psychotropic drugs would be included in the Drugs and Cosmetics Rules and provision would be made to regulate their quantum of production. Distribution of drugs will be permitted through only a limited number of bonafide dealers, as in the case of narcotic drugs. Stringent measure to regulate the prescription for such products have also been recommended. The sub-committee however felt that the provision of the Drugs and Cosmetics Rules were inadequate to deal with the possession of Psychotropic drugs or with the quantitative export of such drugs. For this purpose, the Sub-Committee has recommended that the Drugs and Cosmetics Act should be amended suitably. Dr. Gothoskar however, added that it was possible to amplify the scope of the Dangerous Drugs Act so as to cover Psychotropic substances and also to regulate through this Act, unauthorised possession of such substances by individuals and export of such substances.

Chairman promised to implement the recommendation of the Sub-committee as soon as they are received. He also stressed the need for State Drug Control Administration to be continuously vigilant over

the stock and sale of Psychotropic drugs such as "Mandrax" in and around areas where Colleges and Schools are located.

As regards sub-therapeutic preparations, the Chairman expressed that it would be better to appoint a committee of clinicians and pharmacologists to advise in the matter as is being done in Maharashtra State.

As for repair and maintenance of scientific and laboratory equipment in the state analytical laboratories the Chairman suggested that there were two institutes one in Chandigarh and the other in Calcutta (M/s. National Instrument Ltd., Govt. of India undertaking. Jadavpur, Calcutta - 32) which could help in training the personnel of the states for servicing their equipment. Shri Rangnekar also desired that some guidelines as to the nature/ type of instrutments and the sources from which these could be obtained in the country should be made available to the States. The Chairman agreed to provide information in this respect.

On the misuse of brand names of drugs, the Chairman impressed upon the members that they should insist on National Formulary being adopted for purchasing the drugs mentioned therein. The medical profession was not yet prepared for the abolition of brand names. The best thing, he said, would be to prepare the medical profession to promote the use of generic names in prescribing.

At Dr. Mishra's instance the Committee unanimously passed the following resolution :-

> "Considering the increased incidence of spurious drugs, particularly in States which do not have well organised drug control machinery.
>
> Viewing with alarm the press reports on the increasing abuse of Psychotropic substances particularly by the younger generation.
>
> The Drugs Consultative Committee resolves that
>
> a. The State Governments should be advised to establish special mobile squads manned by plain clothed watchers and police personnel and equipped with facilities for wireless communi-

cation for investigating offences relating to the manufacture, sale and distribution of spurious drugs and the Central Govt. should extend financial assistance to the States for setting up such squads :

b. the recommendations made by the Sub-committee of the Drugs Consultative Committee for exercising a control over the manufacture, distribution and sale of Psychotropic substances should be accepted by the Government and the necessary amendments proposed in the Drugs & Cosmetics Rules made expeditiously so that stringent control over the import, quantitative production, distribution and use of these substances which are being abused, can be exercised. The provisions of the Dangerous Drugs Act should also be amended to cover Psychotropic substances so that the unauthorised possession by individuals and exports of these substances can be controlled under its provisions".

The regular agenda was then taken up for consideration of the Committee.

ITEM NO.1

Confirmation of the minutes of the fifteenth meeting of the Drugs Consultative Committee.

The minutes were confirmed.

ITEM NO.2

Action taken on the recommendations made by the Drugs Consultative Committee at its fifteenth meeting. (Annexure - I)

The Chairman read out the note on action taken. The following decisions were taken :-

(i) **Storage Conditions of Antibiotics.**

The Chairman said that the samples of anti-biotics drawn and tested upto 30-1-72 in the first phase of the sampling programme indicated that the antiboitic preparations, when stored at room temperature in different parts of the country, keep well and are quite stable. He said that before taking final view, it would be better to await the results of the test on the next lot of samples during the second phase of the study.

(ii) **Use of Paraphenylene diamine in hair dyes.**

Shri Rangnekar stated that the manufacturers of hair dyes in Bombay had represented to him against the melting point range of 145° - 147°C for pure Paraphenylene diamine, as recommended by the Drugs Consultative Committee earlier. The manufacturers felt that the melting point range varied from book to book and that paraphenylene diamine of 99.2% purity manufactured by Farbenfabriken Bayer A.G.W. Germany had a melting point between 139.5°C to 140°C. He felt that it may be necessary, to modify the specifications with regard to the melting point range for the pure dye.

The Chairman said that this point had been examined by DR. Kaul, Dy. Drugs Controller (India), East Zone, Calcutta and his view was that as the Dutch Govt. regulations also permit a lower melting point should be fixed at 140°C provided the dye melting at 140°C is absolutely free from impurities. The Committee agreed that the melting point could be fixed at

140°C after the states of Maharashtra and Gujarat consult with the manufacturers of hair dyes in their states and confirm that the melting point of 140°C will be acceptable to them.

(iii) Central Drugs Control Organisation and the Inspectorate - the question how best the inspectors could assist the States in ensuring uniform and stringent enforcement of the provisions of the Drugs & Cosmetics Act & Rules thereunder.

It was decided that the working paper prepared by Shri P. Balasubramanyan, (Convenor) of the sub-committee, (appointed by the Drugs Consultative Committee to examine the question) in consultation with Shri Rangnekar, should be finalised after taking into consideration Dr. Kar's views in the matter. Shri Rangnekar felt that it would be helpful if the Chairman could also be present at the final meeting.

(iv) Consideration of the measures that should be taken to prevent the misuse of spirituous medicinal preparations.

The Chairman said that it was unfortunate that the sub-committee which was to survey the conditions responsible for misuse of alcohol and suggest remedial measures had not been able to meet and hoped that it would complete its deliberations soon.

(v) Incorporation of Good Manufacturing practices under the Drugs and Cosmetics Rules. (Annexure - II)

The report of the sub-committee on the subject was considered. The Committee agreed that, subject to the following changes, thereport should be accepted :-

i. In para 4 of Section VI of Annexure - I relating to "Manufacturing Controls and Directions" vide page 6 of the Annexure, the words "the following precautions shall be observed to prevent contamination" may be amended to read as "The following measures shall be adopted to prevent contamination

or check observance of measures taken in this regard as the case may be :-"

ii. In Item (iii) under Para 1 (a) of Annexure II the vide page 1 of Annexure II the words "Capsules, dragees and powders" should be inserted between the words "tablets" and in final containers".

VI. Control over the Approved Testing Laboratories

The Chairman stressed the need for controlling the "Approved testing laboratories" and suggested that the desired objective of exercising necessary control and check over testing laboratories could be achieved by prescribing the conditions of approval of such laboratories under the Drugs and Cosmetics Rules. The Draft amendments to the Drugs and Cosmetics Rules recommended by the Sub-Committee were considered and agreed to, subject to the incorporation of the following changes in the report :-

(i) In the 'Explanation' given under sub-rule 2 of Rule 151 (a) at page 1 of the Annexure, the words "including homoeopathic drugs" should be inserted between the words "drugs" and "or Cosmetics".

(ii) In Rule 151 (C) at page 3 of the Annexure, the word "cancelled" may be substituted by the word "withdrawn" and the period of "3 years" as specified therein amended to read "2 years".

The proviso under Rule 151 (c) may be amended to fall in line with similar provision relating to manufacturing and sales licences under the Drugs & Cosmetics Rules as amended by the Govt. of India, Ministry of Health & Family Planning Notification No.X-11014/12/72-D dated 5th June, 1972 and provide for levy of additional fees on a monthly rate for a period of 6 months from the date of expiry of the approval. If this is done, a proviso will also have to

be appended in this regard to sub-rule 1 of Rule 151 (a) and the additional fees payable per month specified separately for renewal of the approval in the case of approval for testing of (i) drugs specified in schedule C and C_1 and (ii) other drugs & Cosmetics.

(iii) In para 'g' under Rule 151 (D) at page 4 of the annexure, the words "as well as the licensing authority is located" should be deleted in view of the decision taken to delete Rule 151 (K).

(iv) Sub-clause 2 of Rule 151 (J) at page 6 of the Annexure may be recast so as to provide for appeal to the State Government.

(v) Rule 151 (K) at page 6 of the Annexure should be deleted.

It was also agreed that the report of the sub-committee should be revised in the light of the above changes and the revised report circulated to the members.

ITEM NO.3(C)

Incorporation of additional provisions in Schedule M to the Drugs and Cosmetics Rules in respect of space and equipment for the manufacture of (i) absorbent Cotton Wool (ii) Tinctures (iii) Acids (iv) Fine Chemicals (v) Disinfectants and (vi) insecticides. (Annexure IV)

The Committee noted the Sub-committee's recommendation that it would **not** be possible to lay down the minimum requirements in respect of space and equipment for the manufacture of Acids, Fine Chemicals and Insecticides as these categories included a number of items of varying composition and the space and equipment required for their manufacture would depend upon the nature & composition of the items to be manufactured, the processes employed for manufacture and the size of manufacture. the Committee also took note of the sub-committee's recommendations that

it would also not be practicable to lay down any requirements in respect of the minimum equipment and space under Schedule - M for manufacture of Absorbent Cotton Wool in view of different type of equipment being in use by different manufacturing units in the country, the various processes involved etc. Draft amendments proposed by the sub-committee to Schedule 'M' regarding minimum requirements of space & equipment for manufacture of Tinctures and Disinfectants were agreed to by the Committee.

ITEM NO.4 (i)

Review of progress of enforcement of Rules relating to : (a) Ayurvedic and Unani drugs (b) Homoeopathic drugs (c) Cosmetics and (d) the testing facilities for these products.

The progress of enforcement of Drugs Rules relating to Ayurvedic & Unani drugs, homeopathic drugs & Cosmetics etc. was reviewed by the Chairman. he indicated that so far as Ayurvedic & Unani Drugs are concerned, states like Maharashtra, Gujarat, Punjab, Mysore, Orissa and Delhi had already made considerable progress. The Govt. of Kerala were also expected to issue a notification soon to enforce the Rules to control such drugs, he said. The State Drugs Control of U.P. and Madhya Pradesh stated that steps were being taken in their respective states to enforce the Rules relating to Ayurvedic and Unani drugs.

Regarding the Rules relating to homoeopathic medicines, the Chairman stated that a survey of the present position of the enforcement of the Homoeopathic Rules in the various states indicated that these Rules had been brought into force in Delhi, Pondicherry, Kerala, Tamil Nadu, Goa, Daman & Diu, West Bengal, Assam, Gujarat, Orissa, Haryana, Mysore, Bihar, Maharashtra Andhra Pradesh, Punjab and Chandigarh administration. He informed the committee that licences for manufacture and sale of these medicines had also been granted in these states except Pondicherry where no application for manufacturing or sale licences had been received. No manufacturing unit or sale establishment of homoeopathic medicines operates in Himachal Pradesh.

It was agreed that in Rajasthan which had not enforced Ayurvedic & Unani and homoeopathic Rules should taken early steps for their enforcement.

The Committee also recommended that States which have not enforced the Rules for control over cosmetics should do so as early as possible.

ITEM NO.4 (ii)

Consideration of the question of permitting the sale of Ayurvedic and Unani Drugs (manufactured in States where the Rules for control of Ayurvedic and Unani medicines have not been brought into force) in such States where the Rules have been brought into force.

The consensus view of the members was that all States should takel steps to enforce the Rules for control of Ayurvedic & Unani medicines as early as possible. However, till such time as the enforcement of these Rules in certain states is brought into force the Ayurvedic medicines manufactured by bonafide Ayurvedic firms in such states should continue to be permitted to be sold in other states where the Rules relating to quality control over Ayurvedic & Unani drugs have already been brought into force.

ITEM NO.5

Proposal to introduce a rule in the Drugs and Cosmetics Rules to regulate and control the activities of approved laboratories which are engaged in the testing of drugs and pharmaceuticals as per the standards laid down in the Drugs and Cosmetics Rules.

The Chairman pointed out to the Committee that the report of the sub-committee setting out the manner in which the activities of the private analytical laboratories which have been approved by the State Drugs Control Authorities should be regulated, had already been accepted by the Committee subject to certain amendments. The only question which still requires to be considered is whether the samples tested by these

labortories should be taken by the staff of the analytical laboratories instead of the samples being sent to the laboratories by the manufacturers. The Committee felt that while it would be ideal if analytical laboratories pick up samples, such a procedure may not be practicable especially if the manufacturers are located in outstations.

ITEM NO.6

Samples of drugs manufactured by licensee situated within other State than the one in which the sample is seized and declared sub-standard by the Government Analyst.

The Drugs Controller, Himachal Pradesh stated that samples of certain preparations especially vitamin preparations, had been reported to be not of standard quality and that whenever he brought such cases to the notice of the Drug Control authorities of the State where the manufacturers are located, no action was taken by the latter on the plea that the reference samples available with the manufacturers were of standard quality. He enquired about the course of action that should be taken by him in such cases.

After discussion, it was decided that :-

(i) the batch which was reported as not of standard quality on test should be withdrawn from the market.

(ii) In case it is found that the reference samples with the manufacturers are of standard quality and the drugs moving in the market are not, the Drugs Controller of the State where the drugs are moving may refer the case to the Zonal Officer for making suitable investigations.

The Drugs Controller, Himachal Pradesh also desired to have technical advice on matters relating to enforcement of quality control measures and for administration of Drug Control in his State. The Chairman assured him that he would depute the Zonal Officer, North Zone to Himachal Pradesh to study the specific problems and help him.

ITEM NO.7

Provision for sending samples of drugs to the State Drugs Controller - Amendment of Section 23 of the Drugs and Cosmetics Act.

The Drugs Controller, Himachal Pradesh stated that under Sec.23 of the Drugs and Cosmetics Act there was no provision for referring any part of the sample to the State Drugs Controller where the manufacturers is located. This gave scope for manufacturers to disown the sample seized and reported upon adversely or put forward false please that the control sample maintained by him is of standard quality. He desired that section 23 should be suitably amended.

The other State Drugs Controllers stated that they had not faced any difficulty so far in regard to Section 23. The Chairman stated that unless it was absolutely necessary the Drugs and Cosmetics Act should not be amended.

ITEM NO.8

Definition of raw materials in the Drugs and Cosmetics Act and Rules.

Shri Narasimhan stated that under the Drugs and Cosmetics Rules, raw materials are required to be tested. Since the 'raw material' has not been defined in the Pules, it is difficulty to make manufacturers test pharmaceutical aids used in drug formulations.

The consensus view of the members was that "raw materials" are also deemed to be drugs within the meaning of Section 3(b)(i) of the Drugs and Cosmetics Act and that no amendment to define the term 'raw material' was therefore necessary.

ITEM NO.9

Colouring and flavouring materials.

Shri. Narasimhan desired that some guidelines should be laid down as to what colours and flavouring materials should be permitted to be used in medicines as also the specifications for them.

It was mentioned that the list of colours permitted to be used in drugs was being laid down in the Drugs and Cosmetics Rules and that the standards for these colours are given either in the Prevention of Food Adulteration Rules or in ISI specifications. These standards, the Committee agreed, should be followed by manufacturers.

ITEM NO.10

Powers of Inspectors to draw samples of raw materials.

It was mentioned by Shri Narshimhan that under the Drugs & Cosmetics Act 1940 Drugs Inspectors are empowered to draw samples of drugs but that they have no powers to draw samples of raw materials. This, he said, seriously hampered investigations and desired that inspectors should be vested with powers to draw samples of raw materials as well.

The Chairman pointed out that raw materials are deemed to be 'drugs' within the meaning of Section 3(b)(i) of the Drugs & Cosmetics Act and the Drugs Inspectors can draw samples of raw materials.

ITEM NO.11

Prosecution of Manufacturer by the States where the offences are committed.

Shri Narasimhan stated that the states where manufacturers are located are not willing to indicate the action taken against the defaulting firms or the action taken is not deterrent. He desired that where adequate action has not been taken against such firms the States where offences are committed should be free to initiate action against the manufacturer.

The Chairman stated that notwithstanding the convention that action against manufacturers should be normally taken by the Drugs Controller

of the State in which the manufacturer is located, circumstances may arise in specific cases where action in the State where the offence was detected may have to be initiated. Similarly, in cases where the offence had assumed a certain measure of local importance, the normal convention in regard to prosecutions or other means may have to be by passed and the state where the deficiences or offences were detected may have to take action.

ITEM NO.12

Particulate matter in transfusions - use of second hand bottles.

Shri Narasimhan, Dy. Drugs Controller, Tamil Nadu, stated that use of second hand bottles and poor quality plugs were responsible for complaints regarding presence of particulate matter in transfusion bottles. He desires that measures on an All-India basis should be taken in regard to these aspects.

The Chairman pointed out that this point had already been considered earlier at the fourteenth meeting of the Drugs Consultative Committee held at Panaji, Goa. The Committee reiterated its earlier recommendation that second-hand bottles should **not** be allowed to be used. The Committee however saw no objection to manufacturers of transfusion solutions being permitted to recall their bottles from hospitals etc. and filling them.

ITEM NO.13

Issue of Press Release.

Shri Narasimhan Dy. Drugs Controller, Tamil Nadu, stated that when drugs cause serious reactions and also death, it **may** become necessary to issue Press releases to warn the doctors and public against the use of such drugs. He desired that some specific provision should be made in the Drugs & Cosmetics Act to safeguard the interests of the Drug Control authorities against legal claims for dangers in such cases.

The Committee felt that where public health was in jeopardy,

press notes can be issued in terms which could warn medical profession and the public that suspicion on has been cast on the quality safety of a product and that pending confirmation of this suspicion and in the interests of public health, the withdrawal from use of the product is advisable.

ITEM NO.14

Repacking of Schedule C (i) drugs.

The Committee reiterated its earlier decision that there is no specific provision in the Drugs & Cosmetics Rules for repacking of Schedule C (I) drugs and that as such repacking of Schedule C (i) drugs should not be permitted.

ITEM NO.15

Approval of an item for manufacture which is official and appears to be sub-therapeutic.

Shri Pany brought to the notice of the Committee that manufacturers apply for marketing of Pharmacopoeial preparations in doses which are lower than the "Usual dose" given in the monograph of the pharmacopoeias or which are intermediate between lower and higher dosage levels specified therein and desired to know the procedure that should be followed in regard to such preparations. The Chairman pointed out that this question was earlier referred to us by the Ministry of Finance as it was linked up with the question of levy of excise duty of patent and proprietary medicines. He stated that the following decisions were taken :-

(i) In case of preparations where the pharmacopoeia lays down the "Usual Strength" and also specified the dose range, the preparations marketed in the "Usual Strength" or in a strength which falls within the dosage range specified therein may be deemed to be pharmacoipoeial.

(ii) Where the pharmacopoeia prescribes a dosage range for a preparation without specifying any "Usual Strength" the

preparation should be in a strength which shall not be lower than the lowest dosage given in the pharmacopoeia.

(iii) Where a preparation is marketed in a strength lower than the dose specified in the pharmacopoeia and the manufacturer takes the plea that the preparation is meant for paediatric use, evidence in support of marketing a preparation in lower strength should be adduced by the manufacturer. The paediatric dosage given in the Indian Pharmacopoeia or the National Formulary of India should be considered as guidelines by the administration. In addition, the manufacturer of such preparations should also be required to show a distinguishing legend on the label reading, "For use of Children Only".

(iv) In the case of all preparations covered by the Pharmacopoeias irrespective of whether the "Usual Strength" is prescribed or not, where preparation marketed by manufacturer contain drugs in quantities higher than the maximum dose prescribed in the pharmacopoeia such a preparation should be considered as a pharmacopoeial preparation. The Committee agreed that the above decision should be adopted for guidance.

ITEM NO.16

Practicability of enforcement of the latest amendment to the Drugs & Cosmetics Rules regarding retail packing of all drugs by manufacturers.

Shri Pany, stated that the latest amendment to Rule 105 of the Drugs and Cosmetics Rules requires that all drugs should be made available for sale in retail packing. He stated that manufacturers in his state find it difficult to comply with the requirement of Rule 105 as amended in view of the non-availability of strip-packing material and moisture proof cellophane paper. He said that manufacturers also felt that enforcement of the amendment would also increase the cost of production and desired to know whether considering the difficulties of the manufacturers the

enforcement of the Rule could be deferred or with held.

The Chairman explained that loose sale of tablets and capsules from bulk containers provided scope to unscrupulous dealers to substitute drugs and as such it would be necessary that all drugs should be made available in retail packing.

The Committee decided that the enforcement of the amended Rule 105 should not be withheld and that the enforcing authorities should remain firm in implementing it.

ITEM NO.17

Freezing of stocks of drugs which are suspected to be adulterated or spurious.

Shri Pany stated that certain circulars to State Drugs Control Administration advised the freezing of stocks of drugs which are suspected to be spurious, misbranded or adulterated. He expressed difficulty in freezing stocks of such drugs in the absence of any specific provision in the Drugs & Cosmetics Rules for this purpose and desired that a suitable rule should be incorporated in the Drugs & Cosmetics Rules for the purpose.

The Chairman stated that sub-section (c) of Section 22 of the Drugs and Cosmetics Act permitted Drugs Inspectors to prevent the disposal of suspect drugs and that this should be adequate.

ITEM NO.18

Provision for space for manufacture of Ayurvedic and Unani Medicines.

ITEM NO.19

Approval of Patent Ayurvedic Drugs.

Since the representation of the State Govt. of Haryana was

not present at the meeting thse items (18 and 19) were **not** discussed by the Committee.

ITEM NO.20

Suggestion that a provision in the Drugs & Cosmetics Rules should be made empowering the licensing authority to ask manufacturers to withdraw the batches of adulterated or misbranded drugs.

Shri C. Gopalakrishnamurthy, desired that a provision should be made under the Drugs & Cosmetics Rules, empowering the licensing authorities to order the withdrawal of batches of adulterated or misbranded drugs.

Shri Rangnekar pointed out that preventing of sale of stocks of suspected drugs could be resorted to under sub-section (c) of Section 22 of the Act. Apart from this the provisions of sub-section (2) of Section 31 could also be invoked whereby the court can be moved for confiscation of stocks in question. In view of these provisions the Committee felt that no further change in the Act or Rule was necessary.

ITEM NO.21

Proposal that Acetyl Salacylic Acid tablets IP should be required to be sold in tin containers to prevent hydrolysis of the product during transportation or storage.

The Drugs Controller, Punjab informed the Committee that certain samples of Acetyl Slicylic Acid tablets taken from the market, on test, were found to be not of standard quality.

The contention of the manufacturing firms in such cases has been that hydrolysis of the product was unavoidable despite all precautions during the process of manufacture. A provision should therefore be made that these tablets should be packed in moisture-proof metal containers.

The Chairman stated that while hydrolysis of tablets cannot

be totally prevented, it was possible to minimise this process if manufacturers took adequate precautions such as (a) dry method granulation (b) avoiding the use of excipients which are hygroscopic (c) carrying out the tableting activities under dehumidified conditions and (d) adopting moisture proof containers and closures with desicating agents lodged inside separately. A leading manufacturer of reputable quality of Acetyl Sliaylic acid tablets has submitted a note in this connection and the Chairman promised to circulate the note to the members. It was further agreed that if despite these precautions the products are found to deteriorate, manufacturers should be compelled to indicate a date of expiry of potency.

ADDITIONAL SUBJECTS DISCUSSED

ITEM NO.22

Reactivisation of State Drugs Advisory Boards.

The Chairman pointed out that representatives of the drug industry had already met the Union Health Minister in Bombay and that one of the points represented by them was that the State Drugs Advisory Boards had not been constituted by many States and that in most of the cases where they were constituted the Boards have not been meeting regularly. The contention of the representatives from the drug industry and the drug trade was that matters relating to the enforcement of the Drugs and Cosmetics Act and allied legislations and the development of the drug industry and drug trade could be attended to efficiently and harmoniously if representatives from the drug trade, the industry, the medical profession and consumer groups are consulted and taken into confidence. The Chairman requested the members to ensure that in their respective States the Drugs Advisory Boards are constituted where such boards have not been constituted so far and to make sure that they meet regularly. On the part of the Central Drugs Control Organisation, he said that Ministry of Health would be approached to address the State Governments again in the matter setting out the composition and functions of such Boards.

At the instance of Shri Rangnekar it was also agreed that proceedings of the Drugs Consultative Committee should also be furnished to the State Government in future. Resolutions passed and the salient recommendations made by the Committee would also be circulated to State Governments.

ITEM NO.23

Use of Screw caps and corks for Homoeopathic Medicines - Recommendations of the Homoeopathic Sub-committee.

The Chairman stated that shortage of good quality corks for bottles of Homoeopathic medicines had recently been considered by a sub-committee of the D.T.A.B. He mentioned that a member of the sub-committee had informed that corks of good quality used in Homoeopathic were earlier imported from Portugal. Since these corks were not now available, some foreign manufacturers were using screw caps made of plastic in place of corks and that it would be in the interests of the Homoeopathic Industry in this country to use similar screw caps for their products. The members were requested to bear this suggestion in mind so that the Homoeopathic medicine manufacturers could be advised accordingly.

ITEM NO.24

Loan Licences for manufacture of fine chemicals.

The question whether loan licences should be granted for the manufacture of fine chemicals was considered by the Committee. It was felt that the question arose mainly for the manufacture of chemicals for which raw materials are being allocated through the I.D.P.L. or cancalised agencies. The consensus view was that firms should set up their own units for manufacture of basic chemicals and that wherever imported and canalised items were required for such manufacture, no recommendations should be made by the State Drugs Control Authorities in favour of loan licensees. Instead, increased allocations may be made in favour of the actual users to help them utilise their capacities to the full. The Committee further

agreed that there should be no objection to granting loan licences for fine chemicals if the raw materials involved are entirely indigenous.

ITEM NO.25

Discontinuance of Abortifacient preparations containing Ergot.

It was brought to the notice of the Committee that certain abortifacient preparations containing Ergot were being licensed for manufacture by certain states and that such preparations were harmful and dangerous. The Chairman informed the Committee that in West Bengal all the manufacturing licences granted earlier for such preparations had been withdrawn and that similar action should be taken by other States. It was agreed that all the States should also implement action in this regard in the same manner as West Bengal.

Ergamin caps (Amber Res and Pharm, Bombay), Ergadol caps (B.P. Lab., Bombay), Erasule caps (Pharmpack, Bombay), Ergotab with Hormones (Jagson Pal, Delhi), Ergoplex caps (Dipsan Lab., New Delhi), Ergacap caps (Mercury Pharmaceuticals, Baroda) were some of the preparations which had been brought to the notice of the Central Drug Control Organisation in this connection.

ITEM NO.26

Check on the misuse of 'Mandrex'.

Dr. P.K. Mishra, Drugs Controlier, Delhi Administration stated that the misuse of 'Mandrex' was wide-spread. In his opinion the use of the drug should be stopped and if this was not possible its production should be drastically curtailed by the manufacturer located in Bombay.

Shri Rangnekar was of the view that merely curtailing the production of the drug would not achieve the desired objective of preventing its misuse but might on the other hand, create a shortage for bonafide use. The correct solution would be to regulate its sale and distribution through

a limited number of bonafide dealers and to bonafide consumers.

The Chairman pointed out that psychotropic drugs have legitimate medical use and have not been banned in any country. He felt that while it would not be desirable to interfere with the production of the drug, steps should be taken to regulate its sale and distribution to curb the misuse of the drug.

After discussion, it was agreed that Shri. Rangnekar would direct the manufacturers of "Mandrex" and similar preparations to furnish every month to other State Drugs Control Authorities, a statement showing the quantities despatched, the particulars of firms to whom the drug is supplied etc. to enable a stringent watch being kept over the sale of the drug and to frequent check of the prescriptions for it. The Chairman requested the members to continue to maintain a special check on the sale of psychotropic drugs by dealers located near schools, colleges and universities.

ITEM NO.27

Control over advertisements of diseases under the Drugs and Magic Remedies (Objectionable Advertisement Act, 1954).

Shri Shanbhogue desired to know whether action can be taken to amend the Drugs and Magic Remedies (Objectionable Advertisements) Act to cover advertisements relating to treatment of the diseases mentioned in the Schedule to the said Act without mentioning any names of drugs. He stated that certain doctors advertise extensively in the newspapers that they treat many of the diseases, covered by the Schedule to the Act, move from station to station, and make big money. Unless such activities are regulated, the public are likely to be cheated.

The Chairman stated that when the Drugs and Magic Remedies (Objectionable advertisements) Act was amended last time, the view taken by the Union Law Ministry on this point was that unless an advertisement specifically mentioned the name of a drug or a drug and connected it with the diagnosis, mitigation, treatement or cure of and of the diseases included

in the Schedule to the Act, it would not be possible to take action under the Drugs and Magic Remedies (Obj. Advts.) Act. It would be advisable, he said, if the Law Ministry of the State Governments could be asked to examine whether action in such cases could be taken under any other Act.

Shri Shonbhogue also reported that treatment of venereal and sexual diseases and other diseases that fell within the purview to the Schedule to the DMR (OA) Act, was being offered through correspondence, newspapers and journals and this invariably resulted in patients medicating themselves.

After discussion, the Committee agreed that details about such malpractices should be collected from the States and that the Union Ministry of Health should be apprised of these activities and the inability of the State Drug Control Organisation to take any action under the Drugs and Magic Remedies (Obj. Advts.) Act and that it would be advisable for the Central Government to examine what action can be taken to regulate such activities.

ITEM NO.28

Supply of drugs manufactured by one hospital to another hospital.

Shri Shanbhogue drew the Committee's attention to item 5-A of Schedule K to the Drugs and Cosmetics Rules which exempted a hospital from taking out a sale licence subject to certain conditions, and enquired whether an inspector could be deputed to check whether the conditions under which the exemption was operative was being observed or not by hospitals.

The Chairman said that Dr. J.L. Kaul, Deputy Drugs Controller (India) East Zone, Calcutta had inspected a number of hospitals in West Bengal and Bihar and that he had not experienced any difficulties. On the contrary several hospitals welcomed such visits and have been getting samples of drugs tested through the Central Drugs Laboratory. Frequent inspection of hospitals and their medical stores would be advisable, as otherwise, the Drugs Control authorities would come in for criticism if some mishap were

to result from the use of sub-standard and or deteriorated drugs. Powers to inspect hospitals, in his opinion, implied powers to enforce the conditions under which hospitals have been exempted from the requirement of taking out sale licences under the Drugs and Cosmetics Act.

ITEM NO.29

Possession of Psychotropic drugs by individuals.

Dr. Khosla, Drugs Controller, Punjab enquired whether possession of Psychotropic drugs such as barbiturates etc. by individuals in quantity for in excess of that needed for personal use could be proceeded with under the provisions of the Drugs & Cosmetics Act and Rules thereunder.

The Chairman stated that no action would be possible under the Drugs & Cosmetics Act. However, if the provisions of the Dangerous Drugs Act are amended to cover Psychotropic substances, unauthorised possession of such drugs by individuals could be controlled. This aspect would be taken up with the Ministry of Finance.

ITEM NO.30

Sale of drugs by hospitals to patients at exorbitant prices.

Dr. Khosla and Shri N. Chandrasekhara Nair, pointed out that several private hospitals sold medicines to the patients at exorbitant prices inspite of the fact that these institutions got such drugs at considerable reduced prices from the manufacturers. They desired that some restrictions should be placed on the activities of such hospitals.

The Chairman stated that if the States furnished a note giving the facts and figures about the points referred to by them, the question as to what action could be taken would be examined.

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

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PART II

ANNEXURES TO THE MEETINGS

ANNEXURE - I

Note on the action taken on the Minutes of the 15th Meeting of the D.C.C.

Item No.2 of 16th D.C.C. Meeting

S.No.	Item No.	Decision Taken	Action Taken
1.	**General Discussions:** Training Programme in quality control of Sera and Vaccines. Special arrangement for training Drugs Inspectors & the State Drugs Control Authorities in so far as control over the quality of Sera & Vaccines is concerned, should be made. At present the States are deficient in this field.	Efforts would be made to arrange for a special training course for Sera and Vaccines at Kasauli.	In pursuance of the decision the first training course was conducted from 11.9.72 to 21.9.72 at the C.R.I. Kasauli. Three officers from the State and two offices from the Central Drugs Control Organisation attended the course. The specific subjects that were covered during the 10 days training course were brought to the notice of State Drugs Control Authorities vide this dte. letter No.38-4/72-D, dated 18.8.72.
2.	Minimum Standards for setting up State Drug Testing Units : Dr. (Mrs.) Khosla, Drug Controller, Punjab felt that if Drugs Consultative Committee could provide and recommend certain	It was agreed that a sub-committee consisting of Shri B.V. Patel (Chairman), Shri Kattishetter (Member) and Dr. Prem K. Gupta (M. Secy.) should work out the details and recommend the minimum standards/ requirements of a drug testing laboratory for Stages.	The Government of India, Ministry of Health and Family Planning and the Planning Commission are now actively considering the question of extending financial assistance to States for establishing **combined** analytical Laboratories for food and drugs.

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	minimum standards to be set up by States in respect of Drug Testing Units, it would be helpful to the authorities to impress upon State Govt. the pattern of Laboratory that should be set up.	to test various types of drugs and that the recommendations should among other things cover the organisational and staffing pattern of such a laboratory, the requirement of space, the facilities to be provided in each of the sections, equipment needed for various tests and the qualifications and the salary scales that should be offered to the Director of the Lab. and other Technical personnel.	Maharashtra State Drugs Control Administration has prepared a Model Plan for such a combined Food & Drug Testing Unit. Shri B.V. Patel, Chairman of the sub-committee set up by D.C.C. at its last meeting also retired w.e.f. 2.8.72. In view of the position set out above, it was **not** considered necessary for the sub-committee to meet. Model Plan for a combined Food & Drug Testing Unit would be circulated to the members in due course.
3.	**Item - 2** Quality of drugs supplied by firms to major drugs purchasing organisations.	Inspections should be conducted jointly by the State and Central Drugs Inspector of firms which supply drugs to major drug purchasing organisations.	The decision taken at the last meeting was circulated to all State Drug Control Authorities vide this Dte. Circulr No.38-6/78-D dated 29.5.72.
4.	**Control over Hospitals**	If the conditions of manufacture in hospitals are such as to pose a positive threat to public health interests, it would be advisable for the Drug Control Organisation to pass on to the State Administrative Medical Officer and to the State Govt. an opinion to that effect.	The Director, C.D.I., Calcutta has requested to arrange for a meeting of the Govt. analysts and the leading manufacturers of cosmetics and suggest specific amendment to Form-34 after consulting all the interest concerned so as to obviate the difficulties of Govt. analysts in reporting on samples of cosmetics in Form-34. The proposal when received will be brought forward for consideration of the Committee.

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5.	Amendment of Form-34 of the Drugs and Cosmetics Rules.	The Director, Central Drugs Laboratory and the head of the analytical laboratories in Baroda and Maharashtra should jointly meet the leading manufacturers of cosmetics and discuss the nature of tests that could practically be carried out on cosmetics and suggest specific amendment to Form-34, item 7 thereof.	The Director, C.D.I., Calcutta has requested to arrange for a meeting of the Govt. analysts and the leding manufacturers of cosmetics and suggest specific amendment to Form-34 after consulting all the interest concerned so as to obviate the difficulties of Govt. analysts in reporting on samples of cosmetics in Form-34. The proposal when received will be brought forward for consideration of the Committee.
6.	**Storage Conditions of Antibiotics**	A decision on the storage conditions of Antibiotics will be taken after the result of the All-India Survey that is being undertaken are known.	This Directorate had formulated a Scheme and circulated it to the State Drugs Controllers, Zonal Officers and the Govt. Analysts to carry out the study on the stability of antibiotic preparations chosen for the purpose and stored at room temperature in different parts of the country vide Letter No. 53-9/70-D dated 29.1.72.
7.	**Standards for surgical Dressings** The consensus view of the members was that the standards for surgical dressings should be realistic enough so that the supply line is **not** adversely affected when these standards are enforced.	The chairman suggested that the comments of State Drugs Control authorities on the amendments to IP monograph on 'Absorbent Cotton Wool' and Absorbent Lint' and draft standards on 'Absorbent guage' and 'Bandage Cloth' which had been circulated by the Dte. to the State Drugs Control authorities should be furnished within a period of one month after consulting the manufacturers of Surgical Dressings in their, states so that the standards for surgical dressings could be finalised in the light of the comments received.	So far as amendments to IP monographs on 'Absorbent Cotton Wool' and 'Absorbent lint are concerned, these are being considered by a Panel of the I.P. Committee for inclusion in the supplement to IP. Draft standards on 'Absorbent Guage' and 'Bandage Cloths' would be revised in the light of the comments received from State Drugs Controllers and the Industry and are proposed to be incorporated in the Drugs & Cosmetics Rules. These draft revised standards will be placed before the D.T.A.B. for its consideration.

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8.	Central Drugs Control Organisation and the Inspectorate the question how best the inspectors could assist the States in ensuring uniform and stringent enforcement of the provisions of the Drugs & Cosmetics Act & Rules thereunder	It was agreed that a sub-committee consisting of the following members should suggest ways and means by which the Central Drugs Inspectors could play a more effective and meaningful role in assisting the States in exercising struigent quality control over drugs particularly those moving in inter state Commerce : Shri M.K. Rangnekar, (Chairman) Dr A.C. Kar, (Member) Shri R. Balasubramanyan (Convener)	Sh. Balasubramanyan, Convener, was requested to take necessary action in the matter and let us have the recommendations of the sub-committee as early as possible. The recommendations of the committee are still awaited. The convener has been reminded to expedite the report.
9.	Consideration of the question whether blood transfusion Assembly receiving sets-disposal type should be considered as drugs.	It was agreed that ISI should be asked to lay down standards for these sets and to arrange for their certification. Thereafter the State Administrative Medical Officers should be asked to buy only those sets which bear ISI certification mark.	The ISI has been asked to take steps to lay down standards for Blood Transfusion Assembly Receiving sets and to arrange for their certification and let this Directorate know the action taken in due course. The State A.M.O's will be asked to buy only these sets which bear ISI certification mark, after hearing from ISI in this regard.
10.	Item - 3(a) Use of paraphenylene diamine in hair dyes.	In the light of the available documents/references, the committee recommended the following safe limits for the content of paraphenylene diamine in hair dyes and also the standards for it:- 1. Maximum limit of 4.00% paraphenylene diamine in hair dyes marketed in solution form.	The decisions taken were brought to the notice of all State Drugs Control Authorities vide this Directorate Circular No.38-6/72-D dated 29.5.72.

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		2. When para phenylene diamine is marketed in powder form, it should be allowed to be sold in a concentration of 20% and in packings **not** exceeding 5 gr. in weight. 3. Only the pure dye with a melting point between 145° - 147°C should be allowed to be marketed. 4. The material should be free from impurities such as p-nitraniline and organic chlorine compounds.	
11.	**Item No.4** Check over quantitative production, sale and distribution of Psychotropic drugs.	After discussion the following decision were reached: 1. A Sub-committee consisting of Dr. P.K. Mishra, Shri B.V. Patel and Dr. S.S. Gothoskar (Convener) should examine whether a separate legislation should be enacted or the existing provisions under the Drugs & Cosmetics Act would be adequate to regulate the quantitative production of psychotropic substances, to ensure their distribution through a limited number of dealers and against prescription from Registered Medical Practitioners and to make it mandatory on the part of manufacturers and dealers to maintain detailed records in the same manner as in the case of narcotic drugs. If however, separate legislation is considered necessary by the sub-committee draft legislation should also be suggested by it. 2. The State Drugs Control Organisations should maintain more frequent check over the sale of Psychotropic drugs especially by dealers located near schools, college and Universities.	1. The sub-committee has met and has prepared a report which would be circulated shortly. 2. It has been suggested to the State Drugs Control Authorities that the Drugs Inspectors of their respective States may be asked to keep a

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			frequent watch on the sale and distribution of Psychotropic drugs and the bonafides of the prescription against which supplies are made. In case there is any indication to show that unscrupulous medical practitioners have been prescribing psychotropic drugs indiscriminately, the question of loging a complaint against such practitioners for disciplinary action with the State Medical Council may be considered. It would be also useful to maintain contact with the local Medical Association and impress its members the need to prescribe Psychotropic drugs to their patients, only when dictated by considerations of therapeutic necessity. This Directorate Circular No.20-29/72-DC dated 6.3.72 refers.
		3. Sampling of 'Mandrax' to Medical practitioners should be stopped.	3. The Managing Director of M/s. Roussel Pharmaceuticals (I) Ltds, Bombay had agreed to stop sampling of Mandrax to the Medical Profession. The Commissioner, F.D.A., Maharashtra had been requested to ensure that sampling of mandrax to R.M.P.'s had been stopped.
		4. Since the Medical practitioners of the indigenous systems of medicines who had been recognised as Registered Medical Practitioners by some State Govts. are reported to be indulging freely in the issue of prescriptions for Psychotropic drugs, Health Ministry should be requested to write to State Govt. concerned suggesting that such Medical Practitioners as have had no academic training in pharmacology and therepeutics of allopathic drugs should **not** be recognised as Registered Medical Practitioners for the purposes of the Drugs & Cosmetics Rules.	The Pharmaceutical journals have been asked to publish suitable insertions in their journals to the effect that in the interest of the public health Psychotropic drugs should be sold by dealers only

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			against prescriptions from Registered Medical Practitioners as required under the Drugs & Cosmetics Rules for information and observance of their members in the drug trade.
			4. The Govt. of India, Ministry of Health & F.P. were requested to impress upon State Govts. that potent drugs and habit forming or addiction forming drugs should **not** be allowed to be prescribed by medical practitioners who do **not** possess any academic qualification, experience and knowledge in the practice of modern medicine, and also to ask the States like Punjab, Rajasthan etc. who have recognised such categories of personnel as falling within the purview of the term "Registered Medical Practitioners" vide Rule 2 (ee) of the Drugs & Cosmetic Rules to withdraw such recognisation. The Ministry have issued necessary instruction to State Health Deptt. in the matter vide their circulr No.X.11017020/ 72-D dated 13.6.72.
12.	**Item No.5**		
	Consideration of proposal from All Manufacturers Or-	The Committee agreed that wherever exporters wanted to show the information regarding the name of the manufacturers, the date of manufacture, the	The three proposals of the Export Promotion Council, to-gether with the decisions taken by the Drugs Consulta-

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	ganisation asking for relaxation in the enforcement of labelling provisions of Drugs and Cosmetics meant for export	date of expiry of potency and the batch No. in the form of a code on the label such a procedure may be agreed to in the case of exporters who are registered with the basic Chemicals and Soap Export Promotion Council provided the details of such codes are furnished to the State Licensing Authorities. Apart from this, particulars of exports made under codes should be furnished by exporters to the State Licensing Authorities as and when the exports are made. The Central Drug Control Officers operating at the ports will also maintain separate statistics of such exports. It was further agreed that the implication of these decisions on the indigenous drug industry should be reviewed after sometime.	tive Committee on these at its last meeting, were initiated to the Govt. of India in the Ministry of Health. In pursuance of the first recommendation, a draft rule suggesting amendment to Rule 94 was proposed for consideration of the Ministry of Health in consultation with the Ministry of Foreign Trad for permitting the export of drugs labelled in code Govt's decision in the matter is awaited.
		2. As regards an earlier request made by the Basic Chemicals and Soaps Export Promotion Council that foreign firms should be allowed to operate in this country against loan licences exclusively for export purposes, the committee felt that from the point of view of Drugs & Cosmetics Act, there should be no objection to the proposal.	Since the implications of this recommendations have to be examined by the Ministry of Petroleum & Chemicals from the overall aspect of the development of the drug industry in the country, the Ministry of Health have been requested to obtain the concurrence of that Ministry in the matter. The Ministry of Health have requested the Ministry of Petroleum & Chemicals to expedite their concurrence in the matter.
		3. The third concession asked for by the Basic Chemicals and Soap Export Promotion Council was that drugs meant for export should not be made to show on the label the words "Made in India". The Committee felt that this was a requirement under the Merchandise Marks Act which was administered by the Ministry of Foreign Trade and that the council should be advised to approach that Ministry in the matter.	The Ministry of Health have been requested to ask the Export - Promotion Council to approach the Ministry of Foreign Trade in the matter.

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13.	**Item No.6** Consideration of the Measures that should be taken to prevent the misuse of spirituous Medicinal preparations.	1. The Chairman was asked to take up the matter with the Ministry of Finan ce at the Centre to write to State Excise Dept s. for regulating release of alcohol and to restrict it for preparations which are necessary for medical practice. 2. To reduce the liberal scale of wastage allowed to manufacturers which offers scope for diversion of alcohol for purposes other than bonafide drug manufacture. 3. and To work in unision with the State Drugs Control authorities in matters relating to release of alcohol and exercising quality control over products processed with alcohol.	At the instance of this Directorate the Joint Secretary, Ministry of Health had written demiofficially to the Chairman, Central Board of Excise & Customs in the Ministry of Finance to write to the State Excise authorities who are incharge of release of alcohol to drug manufacturers on the aspects pinpointed by the Drugs Consultative Committee and also on the manner in which the provisions of the Drugs & Cosmetics Act and the State Excise Legislations could be lightened. Since the reports regarding abuse spirituous medicinal preparations emanated from certain areas in U.P., the Ministry of Finance have written to the U.P. Govt. to take necessary action in the matter and furnish a report in regard to the measures taken in this connection. The Union Minister for Health have also written to the Health Minister U.P. to examine this problem in consultation with the Director of Medical & Health Services UP and the Excise authorities in U.P. and take steps to implement the suggestion already communicated to the Director of Medical & Health Services. The Minister for Health in U.P. has since replied to say that the matter is receiving his attention.

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			The problem of misuse of spirituous preparations which are marketed as drugs can be tackled squarly if Govt. have the power to regulate the supply of alcohol depending upon the essentiality of the preparation and the extent to which it is used in medical practice. If this power is not there the controls that can be exercised under other regulations will not be of a substantial nature to solve the problem. The Ministry of Finance have been requested by the Ministry of Health to obtain the advice of the Ministry of Law and Justice regarding ban on issue of alcohol for manufacture of spirituous medicinal preparations or restriction on the issue of alcohol.
		It was further agreed that a sub-committee consisting of the following members should survey the conditions responsible for misuse of alcohol and suggest remedial measures :- 1. Dr. P.K. Misra, D.C., Delhi, Admn. 2. Adviser, I.S.M., Min. of Health 3. Adviser, Homoeopathy, Ministry of Health 4. Dr. S.S. Gothoskar, Dy. D.C.(I), (Convener)	The sub-committee has not been able to meet so far.
14.	**Item No.7**		
	Consideration of the use of Polythylene containers for packing drugs.	1. It would **not** be desirable to grant permission to pack liquid Oral preparations in polyethylene containers irrespective of the density of the material used for fabrication of the containers as contained in the directive issued by the Commissioner, Food	These decisions have been brought to the notice of All States Drugs Control authorities vide this Directorate Circular No.38-6/72-D dated 29.5.1972.

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and Drugs Administration, Maharashtra State.

The Committee also recommended the following lines of action :-

(a) Permission can be granted for use of high density polyethylene complying with ISI specifications, as well as low density polyethylene complying with code practice given in draft ISI specifications for packing capsules and tablets subject to the following conditions :-

(i) the containers are manufactured from the virgin raw materials.

(ii) the containers should have the minimum wall thickness of 0.5 mm.

(iii) In case of tablets or capsuies packed in high density or low density polyethylene laminated film bags, the minimum thickness in case of low density polyethylene should be 300 guage (75 microns) and in the case of high density polyethylene, the same should be 200 gauge (50 microns).

(b) The manufacturers in their own interest should obtain from polyethylene manufacturers and suppliers, certificates to the effect that the materials supplied by them conform to either draft ISI specifications CDC-17-12 or DOC-CDC-17 (4009) as the case may be and is insert and that the material complies with thickness requirements as stated above

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		(c) Use of low density polyethylene for strip packing of tablets or capsules may be permitted. (d) As regards transfusion solution, it was agreed that plastic containers for these should comply with USP specifications.	
15.	**Item No.8**		
	Nasal Preparations containing Liquid Paraffin.	It was agreed that in view of the adverse effect that are associated with the use of Liquid Paraffin in nasal preparations, it should **not** be allowed to be used in such preparations.	The decision was circulated for the guidance of the Drugs Control Authorities vide this dte. Circular No.38-6 72-D dated 29.5.72.
16.	**Item No.9**		
	Consideration of the question whether products containing hexachlorophene be permitted to be manufactured and marketed in the country in view of the reported toxicity of hexachlorophene through skin absorption.	1. A new rule should be introduced in the Drugs & Cosmetics Rules prohibiting the use of Hexachlorophene in cosmetics preparations. 2. Drug manufacturers should be advised to remove hexachlorophene **from** their preparations and substitute it by an antiseptic which would be equally effective.	1. Draft rule prohibiting the manufacture and import of cosmetics containing hexachlorophene under the Drugs & Cosmetics Act & Rules, have been approved by the D.T.A.B, and are under publication for eliciting public committee. 2. The recommendation made by the D.C.C. has been circulated to all State Drugs Controllers for taking necessary action vide this Dte. Letter No.38-6/ 72-D dated 29.5.72. The latest decision of the Food & Drugs Administration (USA) is to prohibit the use of hexachlorophene in soap and other toiletories. Following this decision, the Ministry of Industrial Development have been asked to consider the imposition

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			of a ban on the import of hexachlorophene.
17.	**Item No.10**		
	Inspection of Manufacturers of sera and vaccines.	If the manufacturers of sera and vaccines do **not** agree with the findings of inspection by a Drugs Inspector, Dr. Thomas, Director, CRI, Kasauli could be asked to under take a record inspection of such manufacturing premises.	The decision taken in regard to inspection of manufacturers of sera and vaccines was circulated to the State Drugs Control Authorities vide this Dte. Circular No.38-6/72-D dated 29.5.1972.
18.	**Item No.12**		
	Sending of samples (first five to six batches) to the approved testing laboratory for rechecking.	If the Licensing authority in a State felt that the testing facilities available with a manufacturer are adequate and better than those available with "Approved Testing Laboratory", sending of samples to the approved testing laboratory for rechecking may not be insisted upon.	The decision taken was brought to the notice of the State Drugs Control authorities vide Circular No.38-6/72-D dated 29.5.72 issued by the Dte. on the subject.
19.	**Item No.17**		
	Repacking of Schedule C_1 drugs.	Repacking of Schedule C_1 drugs is not permitted under the Drugs & Cosmetics Rules Besides, drugs and medicines licensed to A/Users in terms of the ITC policy cannot be sold after repacking or rebottling cases where drugs imported against A/Users licence are repacked, should be brought to the notice of the concerned.	The decision was circulated to the State Drugs Control authorities vide circular No.38-6/72-D dated 29.5.72. All the State Drugs Control authorities have also been requested separately vide this Dte.Circular No.38-6/72-D dated 8.9.72 **not** to permit the repacking of Schedule C_1 items under the Drugs & Cosmetics Rules as agreed to by last meeting.

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20.	**Item No.18**		
	In corporation of Good Manufacturing practices under the Drugs & Cosmetics Rules.	Good Manufacturing practices should be given legal status by inclusion in the Drugs & Cosmetic Rules. A Sub-committee was already engaged in this task and that the amendment in the Drugs & Cosmetics Rules that will be necessary in this connection will be examined on receipt of the sub-committee's report.	The report of the sub-committee on the subject has since been received and circulated to the members of the D.C.C vide this Dte. Letter No.38-21/72-D dated 28.9.72 for comments. It has been recommended by the sub-committee that additional provisions relating to good manufacturing practice should be set out in the form of a new schedule V which has been proposed by the committee. Consequential changes that would be necessary in other rules have also been proposed by the committee. The proposed amendments will be considered by the D.C.C. on 28th & 29th of November, 1972.
21.	**Item No.23**		
	Enforcement of Test of content uniformity and dissolution test.	As regards dissolution test, it was agreed that a paper circulated by the W.H.O. on the subject should be circulated to the members.	A copy of a paper entitled "The Introduction of Dissolution test in Pharmacopoeial Specifications", by Dr. G.B. Engel canberra as published by the W.H.O. was circulated to the members vide this Dte. letter No.38-6/72-D dated 6.6.1972.
22.	**Item No.24**		
	Inclusion of Drugs Testing Laboratories in the Centrally sponsored schemes.	The members were assured that the question of central financial assistance to states for setting up drug testing laboratories will again be taken up with the Planning Commission in the Fifth Five Year Plan.	The Minister for Health & F.P. had written to Minister of Planning regarding the question of giving central assistance to States for building up their analytical laboratories.

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			The Planning Commission has since agreed in principle to provide Central assistance for the purpose. Tentative proposals for providing financial assistance to States for setting up combined Food and Drugs Laboratories have been included in the fifth five year plan proposals.
23.	**Item No.26**		
	Post Import check of imported raw materials.	The Chairman conceeded that there might be certain genuine difficulties in carrying out post-import check on the use of imported raw material by manufacturers, but such checks should continue to be carried out as they help in keeping a watch over the utilisation of raw materials imported from abroad.	The decision was brought to the notice of all the State Drugs Control authorities vide this Directorate circulars No. 38-6/72-D dated 29.5.72.
24.	**Item No.27**		
	Control over the approved testing Laboratories	The Chairman suggested that it would be advisable to wait for the report of the sub-committee which is considering the question of exercising control over private Laboratories which undertake testing of drugs from manufacturers who do not have their own testing facilities. Such laboratories should be licensed under the Drugs and Cosmetics Rules and conditions imposed on their functioning. Such a provision will facilitate the revocation of licences granted to these laboratories wherever considered necessary.	The report of the sub-committee on licensing of Testing Laboratories has been received and circulated to the members vide this Dte. Letter No. 38-21/72-D dated 28.9.72 for comments The sub-committee is of the view that Drugs & Cosmetics Act does not empower the Central Govt. to lay down rules for licensing of Testing Laboratories and has suggested that the desired objective of exercising necessary control and check over testing laboratories could be achieved by prescribing the conditions of approval of such laboratories under the Drugs

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			& Cosmetics Rules. Draft amendments have been proposed by the sub-committee in this regard in the form of part XV (A) to Drugs & Cosmetics Rules. The report of the sub-committee will be considered by the Drugs consultative Committee on the 28th & 29th November, 72.
25.	**Item No.31**		
	Manufacture of preparations containing Ayurvedic and allopathic drugs.	1. The State Drugs Controllers should ensure that the ingredients used in such preparations are pure and conform to pharmacopoeial standards if they are included in any pharmacopoeia. 2. The Adviser ISM should be asked to introduce a rule under Chapter IV A of the Drugs & Cosmetics Act to the effect that where ingredients such as paraffin jelly, Eucalyptus oil, menthol etc. are used for the manufacture of Ayurvedic (including Siddha) and unani medicines, the standards for such material should be those given in the pharmacopoeia recognised under the other chapters of the Drugs & Cosmetics Act.	1. This decision was circulated to the State Drugs Control authorities for information vide thid Dte. Letter No. 38-6/72-D dated 29.5.72. The Adviser, ISM was requested to refer the suggestion made by the Drugs Consultative Committee to the Ayurvedic Drugs Technical Advisory Board for its consideration. He has informed us that the D.T.A.B. has agreed to the proposal and steps are now being taken to introduce a new rule in chapter IV. A of the Drugs & Cosmetics Act.
26.	**Item No.34**		
	Rule 65 conditions of Sale Licence-provision for containing photographs of qualified persons.	The licensing authority should issue identity cards with photographs to those who are accepted as qualified persons or "Registered Pharmacists" under the Rules and the latter should be made to carry the identity cards with the photograph on their person. Such qualified persons should also be required to wear clean white overalls while working on the sales premises.	The recommendation of the Committee was circulated to the State Drugs Control authorities vide this Dte. Circular No.38-6/72-D dated 29.5.72 for necessary action.

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27.	**Item No.42**		
	Question of laying down guidelines for the Control of humidity and temperature.	The Chairman promised to make available to the Delhi Drugs Control Administration suitable guidelines in this regard.	The Assistant Drugs Controller North Zone, Ghaziabad had (vide his letter No.NZ/GMP/72/653 dated 10.7.72) written to State Drugs Controllers, North Zone including Delhi in the matter, giving the necessary guide lines.
28.	**Item No.46**		
	Amendment of Rules 65 showing of Batch No. on Cash Memo.	The Committee agreed to the suggestion that under Rule 65(3)(f), it should be obligatory on the part of dealers to show the name of the manufacturer and the batch number in the case of Schedule H drugs as is the case with the drugs specified in the Schedule C or Schedule L.	The necessary amendment to Rules 65(3)(f) to make it obligatory to mention the name of the manufacturer and 'Batch No.' as regards supplies of Schedule H drugs in the prescription register, has been referred by the Govt. of India, Ministry of Health to the D.T.A.B further action will be taken in the matter after the views of the D.T.A.B. are known.
29.	**Item No.48**		
	Amendment of Rule 65 (17) stocking of time expired drugs.	The Committee agreed that time expired drugs in a sales establishment should not only be stored separately from the trade stock as per the proviso to Rule 65 (17) but that suitable warning that these stocks are not for sale should also be exhibited so that the stocks are not removed for sale or distribution through any misunderstanding. It was further decided that Rule 65 (17) should be amended suitably.	Necessary draft amendment to Rule 65 (17) of the Drugs and Cosmetics Rules has been referred to the Ministry of Health for consideration of the DTAB. Further action will be taken after the views of the D.T.A.B. are known.

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30.	**Item No.51**		
	Provision for suspending manufacture when its a threat to Public Health.	The Committee agreed to the suggestion that in the Drugs & Cosmetics Rules provision should be made enabling the licensing authority to direct a licensee to suspend or modify manufacturing activity or recall a drug distributed by a manufacturer if in the opinion of the licensing authority such a decision was warranted in the interest of public health. At the request of the Chairman, Sh. Rangnekar agreed to suggest a suitable draft rule for this purpose.	Sh. Rangnekar had been requested to suggest a suitable draft rule as agreed to and forward it to us for further necessary action.
31.	**Item No.53**		
	Standards for Oral Polio Vaccine.	The Comittee agreed that standards of quality, purity and strength for Oral Polio vaccine should be incorporated in Schedule F.	Draft monograph in respect of standards of quality, purity and strength for Oral Polio Mylitis Vaccine has been obtained from the Director, Pastear Institute Conoor. The views of the Haffkine Institute, Bombay on the draft monograph have also been obtained.
32.	**Item No.50**		
	Amendment of Rules to lay down licence fee for test licences.	It was agreed that a licence fee of Rs.15/- should be made applicable for licences to manufacture drugs for examination test or analysis.	A proposal to amend Rule 90 and Form 12 of the Drugs & Cosmetics Rules to provide for a licence fee to manufacture Import drugs for examination testor analysis has been referred to the DTAB for its consideration. Further action in the matter will be taken after the views of the DTAB are known at its next meeting.

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33.	**Item No.66**		
	Stability of Pharmaceutical preparations including B-Complex Inj.	If any drug preparation showed precipitation of particulate matter, it should be deemed to be not of standards quality and should be withdrawn from the market. If the manufacturer is located in other States, particulars of such parties should be communicated direct to the State Drugs Controllers concerned or to the Central Drugs Central Organisation. It is the responsibility of the State Drugs Control Authority concerned to make sure that proper stability studies with the preparation are carried out.	The decision taken in the matter has been circulated to all State Drugs Control authorities vide this Dte. Circular No.38-6/72-D dated 29.5.72 for appropriate action.
34.	**Item No.67**		
	Question of Grant of retail Drugs licences to the Registered Medical Practitioners.	The medical code of ethics forbids Registered Medical Practitioners from practising medicine and also engaging themselves in the sale of drugs across the counter. Such Registered Medical Practitioners should **not** be granted retail sale licences.	This decision has been circulated to the participating of the D.C.C. vide this Dte. Circular Letter No.38-6/72-D dated 29.5.72.
35.	**Additional Items**		
	Item No.72		
	Assay of ingredients contained in patent and proprietary medicines.	Methods for the qualitative and quantitative assay of ingredients contained in patent and proprietary medicines should be called from the manufacturers and got verified before allowing such preparations to be manufactured.	The decision has been brought to the notice of all State Drugs Control authorities vide this Dte. Letter No.38-6/72-D dated 29.5.1972.
36.	**Item No.73**		
	Action to prohibit manufacture of Penicillin Skin	In view of the sensitivity reactions resulting from the use of Pencillin skin ointment, such preparations should be discouraged from being manufactured.	

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	ointment and tablets of sulphanilamide.	The State Drugs Control authorities were asked not to recommend raw materials for the use of these preparations. Manufacturers using sulphanilamide in their formulations should be asked to discontinue its use in formulations gradually since it was known to produce toxic symptonis and had been superseded by more effective and less toxic sulpha drugs.	These decisions were brought to the notice of the State Drugs Control authorities vide this Dte. Letter No.38-6/72-D dated 29.5.1972.
37.	Subject relating to Drugs Price Control Order. (i) Study of the Drugs (Price Control) Order, 1970 on the medicines purchased by hospitals.	It was suggested that in order to find out whether hospitals and dispensaries stand to gain under the Price Control Order, a selected study of a few hospitals should be undertaken.	The Ministry of Petroleum & Chemicals conveyed that the study should be made through the field staff at the disposal of the Drugs Control Deptt. This Dte. had accordingly written vide circular No.14-13/72-D dated 27.4.72 to all State Drugs Controllers to study the quantities of various drugs (a list of which was sent) purchased by hospitals in their respective states before and after the commencement of the order during 12 months and indicate the extent upto which the drugs bill of these hospitals has been influenced. So far information in respect of drugs purchased by certain Hospitals in Maharashtra State & Bihar has been received This limited information shows that hospitals have been able to obtain chloramphenicol, Tetracycline, Benzathine Pencillin Injection. Normal saline solution, water for Injection, APC tablets, Pheniramine Tablets at prices which are 27% lower than

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			those previously obtained by the hospitals during the earlier year. The hospitals had however to pay more in the case of Procaine Penicillin Injection, Streptomycin Sulphate 1 gm., vials, Di-iodobydroxy quinoline Tabs, PAS grannules, INH Tabs. Sulphadiazine Tabs, Sulphadimidine Tabs. upto 7 to 23%. A final assessment of the effect of the Price Control Order on the drugs bill of hospitals can be made only on receipt of replies from most of the States.
	Change in the Status of Dealers		
	(ii) Shri B.V. Patel and Sh. Pany stated that they know of cases where manufacturers had considered certain dealers as "wholesalers" before the Prince Control Order came into force and that the status of such firms had been changed after the introduction of the Order.	Shri Grover stated that if the names of such firms are brought to the notice of the Ministry of Petroleum Chemicals the matter would be taken up with the manufacturer concerned.	(This Directorate had written to all State Drugs Control authorities vide this Dte. Circular No.38-5/72-D dated 20.5.72 to furnish specific cases where firms were considering certain dealers as "wholesalers" before the promulgation of the order but have considered them as retail dealer subsequently after the order came into force. Only the Drugs Controller, Maharashtra and Director of Medical & Health Services Manipur have replied to say that they have no such cases to report. Replies from other states are awaited.

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	(iii) Shri Rangnekar Commissioner, F.D.A., Maharashtra State represented that certain manufacturers are said to have included charges such as insurance, freight, Packing, forwarding etc. while supplying drugs to dealers outside the States and enquired whether such a practice was in consorance with the provisions of the Order.	Shri Grover said that he would get the matter examined and inform the committee of the legal position.	The note containing the decision was sent to Shri Grover for taking appropriate action. He has been requested to communicate the legal position in regard to the point raised by the Commissioner, F.D.A., Maharashtra for information of the members.

ANNEXURE - II
(Item No.2 (v) of 16th D.C.C. Meeting

REPORT OF TEST SUB-COMMITTEE OF THE DRUGS CONSULTATIVE COMMITTEE ON OBSERVANCE OF GOOD MANUFACTURING PRACTICES

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1. A Sub-committee consisting of the following members was set up by the Drugs Consultative Committee at its meeting held at Cochin on the 19th and 20th September, 1968 to consider the question of laying down necessary provisions in the drugs and Cosmetics Rules for the purpose of ensuring observance of Good Manufacturing Practices by drug manufacturers :-

   1. Shri M.K. Rangnekar, Commissioner, Food and Drugs Administration, Maharashtra State, Bombay (then Director, Drugs Control Administration, Maharashtra State, Bombay) - Member.

   2. Dr. B.B. Sarkar, Director, Drugs Control, West Bengal, Calcutta - Member.

   3. Dr. R.L. Chopra, Drugs Controller, Haryana, Chandigarh - Member.

   4. Shri R. Balasubramanyan, Deputy Drugs Controller (India), Bombay - Member (Convener).

2. The Sub-committee held two meetings i.e. on the 21st and 22nd July, 1969 and the 14th and 15th September, 1970. Both the meetings were held at Pimpri. The first meeting was attended by all the members, but two members vis., Dr. B.B. Sarkar, Director, Drugs Control West Bengal, Calcutta and Dr. R.L. Chopra, Drugs Controller, Haryana could not attend the second meeting for some unavoidable reasons.

3. The draft report of the Sub-committee was circulated for comments by Shri R. Balasubramanyan, Member - Convener to the other members

of the Sub-Committee on the 8th October, 1971. No comments were received from Dr. B.B. Sarkar, As Dr. R.L. Chopra had by then been transferred to another post, certain comments had been made on the draft report by his successor, Shri J.R. Kshetty. These were considered by Shri M.K. Rangnekar and Shri R. Balasubramanyan, as Dr. B.B. Sarkar had since retired from service, and the report finalised.

4. The Sub-Committee considered the following items of the Agenda of the above meeting of the Drugs Consultative Committee, relating as they do to 'Good Manufacturing Practices :-

(i) Agenda Item 32 of the Drugs Consultative Committee Meeting.

Suggestions that further conditions should be incorporated in Rules 74 to and 78 to ensure Good Manufacturing Practices and processing of Drugs.

(ii) Agenda Item 33 of the Drugs Consultative Committee Meeting.

(Excluding the suggestions as regards stipulation of minimum equipment and space for manufacture of cartain drugs viz., Absorbent Cotton Wool, Tincture etc.)

In Schedule 'M', the following additional provisions may be made :-

(i) REQUIREMENT OF FACTORY PREMISES

B. **BUILDING**

The building shall :-

(a) Provide adequate space for the orderly placement of equipment and materials used in any of the following operations for which it is employed :-

(1) The receipt, sampling and storage of raw materials.

(2) Any manufacturing and processing operations performed on the drug.

(3) Any packaging and labelling operation.

(4) Storage of containers, packagaing materials, lebelling of finished products.

(5) Control and production laboratory.

(b) Provide adequate lighting and ventilation when necessary for the intended production or control purposes, adequate screening, filtering dust, humidity, temperature and bacteriological controls.

(c) Provide suitable housing for any animals, when necessary ., After (H) following provisions may be included :-

(I) **Packaging and Labelling :**

Packaging and labelling operations shall :-

(a) Be performed with adequate physical segragations of such preparations from operations on any other drugs to avoid mix ups.

(b) Provide that each type of labelling used shall be stored in a manner that avoids mix-ups between labellings and shall be checked for identity and conformity to the labelling specifications.

(c) Provide adequate control of the quantities of labelling issued for use with the drug.

J. **RESERVE SAMPLE**

A separate space is to be allotted for storage of Reserve samples. Adequate quantity of Reserve Sample of drugs from each batch shall be retained at least 3 years from the date of manufacturing or one year from the date of expiry, when it is applicable.

(2) **REQUIREMENT OF PLANT AND EQUIPMENTS**

Following para may be inserted :-

"Equipment used for the manufacture, processing, packing, labelling, holding, or control of drugs shall be maintained in a clean and orderly manner and shall be of suitable design, size, construction and location in relation to surroundings to facilitate maintenance and operation for its intended purpose. The equipment should be so constructed

that any surface that come into contact with drugs are suitable in that they are not reactive; additive, or absorbtive to an extent significantly to affect the identity, strength, quality or purity of the drugs."

5. The Sub-committee recommends that the requirements under Good Manufacturing Practices may be set out in a separate Schedule to the Drugs Cosmetics Rules and a provision made under Rules 74, 74-A, 74-B, 78 and 78-A relating to conditions of different manufacturing licences that the licensee should comply with these requirements in so far as they are applicable to the manufacture of the drugs covered by his licence.

6. It is considerd that the suggestion under reference made for incorporation of additional provisions in Schedule 'M', vide Agenda Item 33 above, relate to Good Manufacturing Practices and as such , these provisions should be included in the proposed new Schedule containing Good Manufacturing Practices rather than in Schedule 'M'.

7. A draft Amendment of the proposed new Schedule, Schedule V, relating to Good Manufacturing Practices is placed below, vide Annexure (a).

8. It is recommended that Rules 74, 74-A, 74-B, 78 and 78-A of the Drugs and Cosmetics Rules 1945 may be amended by including a Sub-rule under them to the effect that "the licensee shall comply with the requirements under 'Good Manufacturing Practices' as set out in Schedule V, in so far as they are applicable to the manufacture and testing of drugs covered by his licence".

9. Schedule 'U' to the Drugs and Cosmetics Rules would require certain amendments, in view of the provisions made in the proposed Schedule regarding 'Good Manufacturing Practices'. The necessary amendments are suggested at Annexure (b).

Sd/-
(M.K. Rangnekar)

Sd/-
(R. Balasubramanyan)

ANNEXURE - (a)

DRAFT AMENDMENT OF SCHEDULE RELATING TO GOOD MANUFACTURING PRACTICES

In the Drugs and Cosmetics Rules, 1945 (hereinafter referred to as the said Rules) after Schedule 'U' the following Schedule may be inserted, namely :-

SCHEDULE V

(See Rules 74, 74-A, 74-B, 78 and 78-A).

I. Building

Building(s), where drugs are manufactured, processed, packed, labelled or stored shall :-

(a) Be suitable for the operations being carried out

(b) Not be utilised for any other purpose.

(c) Be rodent Proof and kept free of rodents, vermin, birds and other pests.

(d) Be, if necessary, air-conditioned and maintained at such temperature and under such relative humidity which will not adversely affected the drug under manufacture and storage.

(e) Provided adequate working space and adequate room for the orderly placement of equipment and material used in any of the following operations for which it is employed, so as to minimise or eliminate any risk of mix-ups between different drugs, the raw materials used in Manufacture, labelling or packing materials and to control the possibility of cross-contamination of one drug by another drug that is manufactured, stored or handled on the same premises :-

(1) The receipt sampling and storage of raw materials

(2) Any manufacturing and processing operations performed on the drug.

(3) Any labelling and packing operations.

(4) Storage of containers, labelling and packing materials and finished products.

(5) Control and Production-laboratory operations.

Provided that the total areas reserved for storage of raw materials, labelling and packing materials and finished products shall ordinarily be not less than twice the total area reserved for manufacture.

(f) Provide special rooms or areas for storage of highly toxic drugs and narcotics. Such rooms or areas must be subject to restricted access of personnel.

(g) Provide separate enclosed areas for purposes such as the manufacturing of drugs that can be sterilised in their final containers. These areas should be essentially dust-free, preferably supplied with filtered air at a pressure higher than that in adjacent areas and be subject to restricted access of personnel through an air-lock. The design of such areas, if fearible should be such as to preclude the possibility of mix-up of products intended for sterilisation with those already sterilised.

(h) Provide for manufacturing of drugs that cannot be terminally sterilised, a separate enclosed area specifically designed for the purpose.

(i) Provide suitable housing for animals, if any, used.

(k) Provide for adequate washing, cleaning, toilet and locker facilities.

(l) Provide for separate areas for collection of waste materials, which shall be disposed of at regular intervals.

II. Equipment

1. Equipment used for the manufacture of drugs shall be maintained in a clean and orderly manner and shall be of suitable design, size, construction and location in relation to surroundings to

facilitate maintenance and operation for its intended purpose. The equipment shall :-

(a) Be so constucted that any surfaces that come into contact with drugs are suitable, in that they are not reactive, additive or absorptive to an extent that significantly affects the identity, strength, quality or purity of the drug or the raw materials used in the manufacture thereof.

(b) Be so constructed that any substances required for the operation of the equipment, such as lubricants or coolants may be employed without hazard of becoming additive to drug products.

(c) Be constructed to facilitate adjustment, cleaning and maintenance as necessary to assure the reliability of control procedures, to assure uniformity of production and to ensure the exclusion from drugs of contaminants including those from previous and current manufacturing operations.

(d) Be of suitable size and accuracy for use in any intended measuring, mixing or weighing operations.

2. All equipment used to sterilise products should be monitored by means of recording devices and/or indicators of operating conditions within the equipment. These devices and/or indicators should be initially calibrated and checked at regular intervals by suitable and approved methods.

3. Manufacturing equipment and utensils should be thoroughly cleaned, if necessary sterilised, and kept in accordance with written and specific directions. When indicated all equipments should be disassembled and thoroughly cleaned to preclude they cary over of drug residues from previous operations. Adequate records of such procedures shall be kept.

4. The suitability of the equipment used for aspectic filling should be checked and confirmed at regular intervals. Adequate records of such checks shall be maintained.

III. Sanitation

1. Manufacturing premises shall be maintained in clean and orderly manner, free from accumulated waste, debris, varmin etc.

2. A routine santitation programme shall be drawn up and observed; which shall indicate :-

   (a) Specific areas to be cleaned and cleaning intervals.

   (b) Cleaning procedures to be followed and necessary equipment and materials to be used for cleaning.

   (c) Personnel assigned to and responsible for cleaning operations.

3. No eating, smoking nor any un-hygenic practices shall be permitted in manufacturing areas.

IV. Raw Materials

1. All raw materials to be used at any stage in the manufacture of drugs shall be :-

   (a) Identified and visually examined for damage of container. Any damage likely to prejudice the integrity of the contents shall be reported to and assessed by the quality control department.

   (b) Inventoried and recorded as to their origin, date of receipt, date of analysis and release by quality control department and their subsequent use in manufacture as specified in Schedule 'U'.

   (c) So stored and handled as to assure that dust or particles resulting from such storage or handling do not contaminate other substances or preparatiors in the quality control department.

   (d) Specifically marked as undergoing testing and/or if possible quarantined for eventual release by the quality control department.

   (e) Properly sampled by quality contro. representative.

   (f) Tested for compliance with required specifications.

(g) Release by quality control through written instructions.

(h) Properly and conspicuously marked as accepted or approved and subsequently transferred, if necessary, to the areas designated for storage of approved materials. Materials shall not be transferred from the storage area to any production area unless released by quality control and unless the individual contrainers are duly mrked as accepted or approved by quality control.

2. All rejected raw materials shall be conspicuously identified as such and destroyed or returned to the supplier as soon as possible. Records shall be maintained of their disposal.

V. **Master-Formula and Batch Manufacturing Records**

1. **Master Formula Record**

For each drug a master-formula record shall be prepared, endorsed and dated by an approved qualified person under these rules and shall be independently checked, reconciled, endorsed and dated by a second approved qualified persons. The record shall include :-

(a) The name of the product, a description of its dosage form and a specimen or copy of the label and each other portion of the labelling contained in a finished pack of the drug.

(b) The weight or measure of each ingredient per dosage unit or per unit of weight or measure of such dosage unit, permitted overages or excesses to be included in the formulated batch in respect of the amount of any ingredient should be indicated as such herein.

(c) A complete batch formula for each batch size to be produced from the master-formula record including a complete list of ingredients duly designated by names or codes sufficiently specific to indicate any special quality characteristic, an accurate statement of the weight or measure of each ingredient, regardless of whether it appears in the finished product.

duly taking into account variations permitted in the amount of raw materials necessary in the preparation in dosage form, provided that the variations are stated in the master formula; an appropriate statement concerning and indicating the reasons for, the addition of any calculated excess of an ingredient, an appropriate statement of theoretical weight or measure at various stages of processing and a statement of the theoretical yield.

(d) A description of all vessels, and equipment with their sizes used in producing a batch of drug, and method of cleaning before manufacture.

(e) Manufacturing and control instructions, procedures specification special notations and precautions to be followed. Each step or process is to be stated clearly. All necessary quality control tests and analysis to be carried out during each and every stage of manufacture including the designation of persons or departments responsible for or charged with the execution of such tests and analysis shall be specified.

(f) A description of the final and immediate containers, closures, labelling, packing and finishing materials.

2. **BATCH MANUFACTURING RECORDS**

(a) A copy of the master documents, vide clause (1) of the Para V above or the suitably abridged master documents shall be made for each batch of a drug before it is manufactured. The copy shall be checked before use and signed by the approved qualified person. The manufacture of the batch shall proceed in accordance with these documents.

(b) Batch manufacturing records shall be maintained in respect of drugs as specified in Schedule 'U'.

VI. Manufacturing Controls and Directions

1. Manufacturing operations and controls should be effected under

the supervision and responsibility of qualified persons approved by the licensing authority. Each critical step in the process such as the selection, weighing and measruing of raw materials, the addition of active ingredients during the process; weighing and measuring during various stages of the processing; and the determination of the finished yield shall be performed by a qualified person and checked by another qualified person or if such steps in the processing are controlled by provision, automatic, mechanical or electronic equipment, their proper performance shall be adequately checked by one or more qualified persons.

2. Prior to starting manufacturing activity, a verification shall be made.

   (a) Whether all equipment, utensils and containers have been thoroughly cleaned and/or sterilised, if necessary.

   (b) Whether previous identification has been removed between the batches, and, in continuous batch operations, at suitable intervals, to prevent contamination and mix-ups.

3. All containers and equipment used in producing a batch of drug shall be clearly labelled at all times to identify fully and accurately their contents, the stage of processing when necessary and the batch, and shall be stored and handled in a manner adequate to prevent mix-ups with other drugs.

4. The following measures shall be adopted to prevent contamination or check observance of measures taken in this regard as the case may be :-

   (a) All manufacturing operations shall be confined to separate areas intended for such purposes with complete equipment used exclusively in those areas or provision shall be made to assure that no extraneous contamination or mix-up occurs.

   (b) Sterile operations must be performed in specially designed and constructed areas for their intended purpose as indicated

in clauses (c) and (f) of Para I above.

Whenever through lack of physical separation of operations the possibility exists that unsterilised products could be confused with already sterilised products, containers of batches of product for sterilisation should have attached devices which indicate whether or not the sterilisation process has been carried out.

(c) All operations in which highly potent drugs, including antibiotics are weighed, mixed, micronised, formulated, filled, encapsulated, tabletted etc. should be conducted in confined areas with adequate exhaust systems or areas under negative pressure to proclude drug to drug migration. Adequate precautions should be taken to preclude recirculation of contaminated air.

Appropriate procedures shall be followed to control the hazard of crores contamination of non-penicillin products by penicillin in those factories which manufacture, store or handle penicilin products and non-penicillin products.

(d) In manufacturing areas, clean working uniforms shall be worn over or in place of street clothing.

(e) Contamination of products subject to sterile operations such as prenteral drugs, ophthalmic solutions etc. shall be precluded by either the use of suitable methods such as laminar flow techniques or by the wearing by personnel of clean and sterilised gowns, head-gears, masks, rubber gloves and shoes and by their entry into the manufacturing areas through suitably designed airlocks. Such personnel must also wash their hands in a suitable disinfectant prior to dressing and entering sterile areas.

(f) To ensure the germicidal efficiency of Ultra Violet lamps in use in sterile areas, a record shall be maintained of their burning hours or a periodical check made on the intensity of their energy by means of a suitable U.V. Meter.

(g) Powder materials used for manufacture of tablet shall be sifted before use to prevent contamination with foreign matter.

(h) Water used in the manufacture of liquid oral preparations shall be either Deionised Water or Distilled Water.

(i) Finished Tablets shall be inspected individually for presence of foreign matter, besides chipping capping etc.

(j) Individual containers of liquid oral preparations shall be examined under adequate light against a background of both black and white before and after filling to ensure freedom from contamination with foreign matter.

5. To assure the uniformity and integrity of products, adequate in process controls such as checking the weights and disintegration time of tablets, checking adequacy of mixing, the homogeneity of suspensions and the clarity of solutions shall be exercised. The results shall be checked periodically by quality control staff.

6. A qualified person approved by the licensing authority shall check actual against theoretical yield of a batch of drug and in the event of any significant un-explained discrepancies, he shall prevent distribution of the batch in question and other associated batches of drugs that may have been involved in a mix-up with it.

VII. Product Containers

Suitable specifications, test methods, cleaning procedures and when indicated sterilisation procedures shall be used to assure that container, closures, and other component parts of drugs packages are suitable for their intended use, in that, they are not reactive, additive or absorptive to an extent that significantly affects the identity, strength, quality or purity of the drug and furnish adequate protection against its deterioration or contamination.

VIII. Manufacturing Personnel

1. No person known to be affected with disease in communicable form or to be a carrier of such disease and no person with open lesions on the exposed surface of the body shall be engaged in the manufacture of drugs. Periodic health checks shall be made on the manufacturing personnel and records kept thereof.

2. Whenever necessary manufacturing personnel shall, in order to preclude any possible impairment of their health caused by the handling of hazardous or very potent drugs wear protective clothing, shoes, head-gear, dust masks etc. and this protective clothing shall remain in the area. In some instances, it may be necessary to restrict personnel to their respective and immediate working areas.

IX. Labelling and Packing

Labelling and packing operations shall be adequately controlled to assure :-

(1) that only those drugs that have met the specifications established in the master-formula records shall be distributed.

(2) that the finished products are properly identified by means of a Batch No. or Lot No.

(3) that correct labelling as required under those rules is employed for the drug and shall :-

(a) Be performed with adequate physical segregation of such operations from operations on other drug to avoid mix-ups.

(b) Provide that labelling and packing materials, including leaflets shall be adequately and separately stored to eliminate any risk of mix-ups, and shall be carefully checked for identity, and conformity to the labelling and packing materials specified in the master-formula records both before taking

them into stock and at the time of their issue

Access to these materials shall be restricted to authorised personnel only.

(c) Provide adequate control on the quantities of labels issued for use with the drug. The control should include both destroyed and unused labels.

(d) Provide for destruction under the supervision of an approved qualified person of all unused labels which have been issued to the packing line and have had printed or otherwise marked on them the Batch Number, the date of manufacture or date of expiry.

(e) Provide for an inspection of the facilities to be used prior to labelling drug to assure that all the previously used labelling and packing materials and other drugs have been removed and to prevent mix-ups between drugs during such operations.

(f) Provide for adequate examination of laboratory testing of adequately representative samples of finished products after labelling and packing to safeguard against any error in the finishing operations, and to prevent distributon of any batch until all specified tests have been made.

X. Laboratory Controls

Every manufacturer shall either provide necessary facilities for exercising Laboratory Controls to assure that raw materials, drug preparations in the course of processing and finished products conform to the appropriate standards of identity, purity, strength and quality or make arrangements for the purpose with any institution approved by the Licensing Authority in this regard. Such Laboratory Controls shall include :-

(a) The establishment of Master Records containing appropriate specifications for (i) each raw material used in manufacture

(ii) drug preparations in the course of processing, when required and (iii) finished products, together with a detailed and exact description of the laboratory test procedures to check them, including provision for testing adequately representative samples. Such records shall also provide for appropriate retesting of materials subject to deterioration.

(b) Adequate provision for checking the identity and strength for all active ingredients of drugs, for assuring the sterility of drugs and other substances/articles purporting to be sterile and the freedom from pyrogens of drugs and other substances that should be tested for freedom from pyrogens.

(c) Adequate provision to check the reliability, accuracy and precision of any laboratory test procedures used.

(d) Provision for taking of all samples for quality control by the quality control staff only.

(e) Provision for keeping a reserve sample of atleast twice the quantity of drug required to conduct all the tests performed on the batch of drug for a period of one year after the date of expiry in the case of drugs labelled with a date of expiry and five years in the case of other drugs.

(f) Provision for maintaining complete records of all date concerning laboratory tests performed including the dates and endorsement of individuals making the tests, and provisions for specifically relating the tests to each batch of drug to which they apply. Such records shall be retained for atleast two years after the date of expiry in the case of drugs labelled with a date of expiry and six years in the case of other drugs.

(g) Provision for checking the disposal of rejected raw material, drug preparations in the course of processing and finished products. Records shall be maintained of such disposal.

(h) Evaluation of the adequacy of the conditions for the storage of raw materials, inter-mediates and finished drugs.

(i) Evaluation of the stability of finished drugs and whenever ne sary, of raw materials and inter-mediates, with adequate provision for determining the reliability and specificity of the stability test methods employed.

(j) Establishment of expiry periods on the basis of appropriate stability data.

(k) Evaluation of the suitability in containers in which drugs are marketed to assure that the container is not reactive, additive or absorptive to an extent that would significantly affect the identity, purity, strength or quality of the drug.

XI. Records of Sale and/or distribution

Complete records shall be maintained of the sale and/or distribution of each batch of drug in a manner that will facilitate its recall if necessary. Such records shall be retained for at least two years after the date of expiry in the case of drugs labelled with a date of expiry and six years in the case of other drugs, and shall include the name and address of the pary to whom distributed or sold, the date on which, and the quantity, distributed or sold and the batch number of the drug.

XII. Records of Complaints

Complete records shall be maintained of all written or verbal complaints regarding adverse reactions from use of drug and the quality of drug including any change in physical description, in respect of each product. Complaints shall be evaluated by competent and responsible personnel and where indicated, appropriate measures taken as soon as possible. The records shall indicate evaluation and action taken.