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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 13TH MEETING OF THE DRUGS CONSULTATIVE COMMITTEE HELD ON THE 26TH - 27TH DECEMBER, 1969 AT NEW DELHI

The Chairman thanked the members for making it convenient to attend the meeting. Reviewing the Drug Control activities on an all-India basis since the Committee met last in Cochin in September, 1968, the Chairman stated that in States like U.P., Rajasthan, Haryana, Punjab and Madhya Pradesh, there has been a gradual tightening of Drugs Control measures and manufacturing firms have been subjected to increasing standards of inspection. Firms which did not come upto the required standards have been closed down. In particular, inspection of firms manufacturing tranfusion solutions, antibiotic preparation has been carried out and wherever they were found deficient, manufacturers were asked to improve the manufacturing conditions. he suggested frequent and stringent inspection of firms manufacturing Eye Drops and Eye Ointment throughout the country particularly as the hazards involved in using nonsterile Ophthalmic preparations are serious. Similarly, there is need for a country-wide compaign against chloramphenicol palmitate suspensions which are therapeutically inactive and which should be weeded out.

In Bihar, he felt, the Drug Control Administration requires to be tightened. He was quite appreciative of the deficiencies in that State and offered to extend

could comply with the condition that drugs should be purchased by them from only licensed dealers. Amendments to this list may also be made every month and circulated to the Associations.

Before concluding, the Chairman thanked Shri Chandrasekhran Nair, Drugs Controller, Kerala and the members of his Inspectorate and other staff for the excellent arrangements made by them for the meeting of the Drugs Consultative Committee and the Drugs Conference and for the co-operation extended by them. The Committee also placed on record its grateful thanks to the Government of Kerala for the help extended by them.

It was decided that the next meeting of the Drugs Consultative Committee should be held at an early date at Indore or Jaipur.

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

any help which the State may expect from the Centre.

Coming to the organisational part he stated that Maharashtra had further streamlined its Drugs Control Administration by the addition of police staff to its divisional organisations. In the States like Punjab, Haryana, Delhi, U.P., Bihar, M.P. and even West Bengal the organisation required to be strengthened considerably. Leaving aside West Bengal, the other States must have atleast two well-qualified drug inspectors who have had adquate experience in the manufacture and testing of drugs and in the inspection of manufacturing establishments. Rajasthan, he pointed out, would very soon having qualified inspectors.

Regarding spurious drugs, the Chairman stated that their incidence has become more pronounced now than ever before. In the belt comprising Punjab, Haryana, Delhi, U.P. Bihar and West Bengal, a number of reports of spurious drugs have been received. The Prime Minister, he said, had written to the States on the subject. He proposed to have a separate discussion with the State Drug Controllers of North Zone so that mobile units consisting of representatives from the Drugs Inspectorate and the police could be established for quick action whenever reports of a movement of spurious drugs are received. Turning to the analytical facilities available in the country, the Chairman mentioned that the Central Indian Pharmacopoeia Laboratory, Ghaziabad is now reasonably well-equipped to test non-schedule drugs and is in a position to undertake the testing of samples on behalf of states which do not have adequate testing facilities. The proposal for rendering financial assistance to the States to set up or augment their testing labs was still under consideration.

Speaking on the subject of sampling, the Chairman stated that there was a perceptible change in the pattern of sampling by the States. More emphasis was now being given to the testing of life saving drugs such as antibiotics etc. rather than to vitamin preparations. He suggested that in future sampling should primarily be confined to anti-diabetic drugs, cardiac drugs, tranfusion solutions, antibiotics and ophthalmic preparations. The Zonal Officers would also draw samples from these categories of drugs. A liaison will have to be established between the States and the Centre regarding sampling programmes so that there is no duplication.

The Chairman stated that the states should concentrate on more frequent inspection of manufacturing firms which have entered into rate-contract with the D.G.S. & D. for the supply of medicines to the Government hospitals and other institutions. The aim of the inspections should be to check the quality of those drugs which they supply against the D.G.S & D. rate-contract and also on the ability of these firms to make such supplies without sacrificing the quality. He also suggested that the State Drug Control authorities should frequently inspect the hospitals to ensure that proper storage facilities for thermolabile drugs such as sera and vaccines, insulin are maintained and that time-expired drugs are not stored by them. Discussion may be held with the hospital administrators to ensure compliance with these requirements. He said that the supply of drugs by hospitals had been the subject of Parliament Questions and that in consequence greater vigilance may be exercised by the Drug Control Organisation in this direction.

The annual reviews of the activities of the State Drugs Control Organisation and those of the Zonal and Port Officers of the Central Drugs Standard Control Organisation were thereafter circulated to the Members.

Agenda Item - 1

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

The minutes were confirmed subject to record relating to Item-14 of the minutes of the last meeting being amended to read as follows :-

Item - 14

"The Director, Drugs Control Administration, Maharashtra explained that in his state the practice was that where an item was licensed for manufacture as a "drug" and it was also produced for use in the cosmetic industry, no separate licence for its manufacture as a "cosmetic" was being insisted upon. In case raw-materials for cosmetics which have no use in the drug industry, licenses to manufacture them as cosmetics were being insisted upon. The Committee recommended that the same procedure may be adopted by other states also."

Item - 2

Action taken on the recommendations made by the Drugs Consultative Committee at its last meeting.

The Committee noted the action taken on the recommendations made by the Drugs Consultative Committee at its last meeting. (Annexure - I)

Item - 3

Question arising out of the minutes of the twelfth meeting of the Drugs Consultative Committee.

(a) Question of laying down of guidelines for the enforcement of rule 62(B)2 and 64(2) of the Drugs and Cosmetics Rules, 1945, so as to enable the licensing authorities to use their discretionery powers properly.

The Chairman stated that the question of laying down guidelines for the enforcement of Rule 62(B)2 and 64(2) of the Drugs and Cosmetics Rules, 1945, was discussed at the last meeting of the Drugs Consultative Committee. It was decided to study the regulations followed in France, Goa and Portugal. The regulations followed in France and Goa which had been circulated with the agenda papers indicated that two principles were followed in granting sales licenses in France and formerly in Goa namely (a) licenses were granted on population basis, and (b) the distance between location of these drug stores was defined. This approach was based on the consideration that a pharmacist running a pharmacy should be able to earn a minimum reasonable income. The margin of profit for dealer was also fixed.

The following points emerged during the course of the general discussions :

(a) The States in general have not been restricting the number of licences in Form 20-A and 21-A on the basis of the restrictions set out in Sub-rule 2 or Rule 62 (B). Any departure from the practice followed hitherto may invite resistance from the trade and also lead to legal challanges.

(b) The validity of the restriction placed under Sub-rule 2 of 62(B) is doubtful especially when there is no specific sanction for such restrictions in the Act.

(c) Indiscriminate licensing in Form 20-A and 21-A would affect adversely the financial interests of pharmacies and other dealers, with the result that some of the dealers are compelled to resort to unethical practices such as clandestine purchase of drugs at reduced prices from unauthorised sources, etc.

(d) Restricted licences have to be encouraged mainly on the ground that regular chemists establishments are not open round-the-clock, particularly in the suburban and other areas in cities.

After discussion, it was agreed that no uniform guidelines in regard to the implementation of sub-rule 2 of Rule 62(B) can be evolved at this stage. State Drug Control Administration should however ensure that round-the-clock dispensing and supply services are arranged in the principal localities in their States for the benefit of the public. Restricted licences should be granted as far as possible in only those areas which are not served by an adequate number of regular licenses covering the sale of drugs.

The Chairman further mentioned that Associations representing dealers had been suggesting that the grant of sale licences for drugs should be restricted on the basis of population. If the Associations have any specific recommendation to make in this regard their views could be ascertained by the State Drug Control authorities and forwarded for consideration by the Drugs Consultative Committee.

Item - 3(b)

34 (10) of the last D.C.C. Consideration of the question of laying down minimum conditions for manufacture of Opthalmic Ointments.

Introducing the subject, the Chairman stated that the Director, Drugs Control, West Bengal, was of the view that the conditions under which the manufacture of Ophthalmic Ointments should be carried out, as drawn up by the

Director, D.C.A., Maharashtra and circulated to the States should have a statutory backing lest they should be challanged in the court of law. Shri B.V. Patel was of the view that the guidelines suggested by the Director, D.C.A., Maharashtra may require modification as more experience is gained in enforcement.

After discussion, the Committee agreed that the minimum requirements for the manufacture of Ophthalmic Ointments drawn up by the Director, D.C.A., Maharashtra may be adopted as guidelines by the State. It was not necessary to incorporate the minimum requirements in the Drug Rules for the present.

Item - 3(c)

Consideration of difficulties experienced by the Govt. Analyst in reporting on Form No.34 of the Drugs and Cosmetics Rules.

The Chairman stated that the Drugs Consultative Committee at its last meeting held in Cochin had considered the difficulties experienced by Govt. Analysts in issuing reports on cosmetics in Form 34. It was agreed that the Director, D.C.A., Maharashtra and Gujarat should consult their Govt. Analysts and suggest the specific changes that should be made in the form.

The Government Analysts of the States of Gujarat and Maharashtra discussed the difficulties encountered in reporting on samples of cosmetics and agreed that :-

(A) Form No.34 should be deleted and instead, Form No.13 with the necessary amendments should be used or alternatively a new Form on the lines of Form 13 should be introduced, so that as in the case of the samples of drugs the samples of Cosmetics can be declared standard/not of standard quality.

(B) To declare a Cosmetics sample as of standard quality or not of standard quality it is essential to lay down standards for the various types of Cosmetics. These can be laid down in the Drugs and Cosmetics Rules just as has been done in the case of disinfectants.

(C) It is also necessary to undertake methods of tests to determine the harmless character of a Cosmetic. In the case of identification of a colour, it is essential that different laboratories should follow as far as possible uniform procedures for testing.

After discussion, the Chairman agreed to obtain the views of the Director of the C.D.L. on specific aspects brought out by the Govt. Analysts of Gujarat and Maharashtra and examine the action to be taken in the matter. Meanwhile, Shri B.V. Patel was also requested to consult his State Analyst and suggest specific proposals regarding (A) & (C) above.

Item - 4

Question whether repacking of cosmetics may be permitted under the Drugs and Cosmetics Rules.

The Chairman stated that the question whether repacking licences for cosmetics should be issued had been raised. Enquiries were made with the Drug Control authorities in Maharashtra, Gujarat and West Bengal regarding the policy followed up in their respective states. While the Director, D.C.A., Maharashtra felt that repacking of cosmetics might be permitted, the Drug Control authorities of Gujarat and West Bengal were not in favour of such a course of action. After discussion, it was decided that while basic cosmetics raw materials such as Nail Polish, Lacquers etc. may be permitted to be repacked, no licence for the repacking of cosmetic formulation should be granted.

Item - 5

Consideration of the question of enforcement of the conditions of storage of Drugs as notified by the State Licensing authorities and the difficulties that may arise in enforcing these provisions.

The Chairman recalled that notifications had been issued by the State Drug Control authorities specifying the conditions of storage for drugs. Subsequent to this, the industry and the trade had represented that maintenance of "cool place" storage arragement was difficult and that the storage conditions applicable to vitamins, etc. should be reviewed.

In effect, the Chairman continued while there was no difficulty about enforcement of storage conditions of drugs such as Insulin, sera, vaccines, etc. which required to be maintained in cold storage, the difficulty arises only in respect of vitamins and antibiotics, especially as certain States had asked for wholesale warehouses to be air-conditioned.

Shri B.V. Patel stated that in the next edition of the U.S.P. there might be a reclassification of the range of storage temperatures as under :-

Cool Place	8 - 15°C
Room Temperature	15 - 30°C
Excessive Heat	40°C

He suggested that under the conditions prevailing in this country, room temperature should cover a temperature range of 15 to 30°C and the conditions of storage of vitamins preparations reviewed accordingly. After discussion the Committee agreed that :-

(a) The storage conditions laid down in the next edition of the U.S.P. should be awaited and thereafter the storage conditions already recommended by the DTAB should be reviewed in the light of the requirements set out in that edition of the U.S.P.

(b) So far as vitamins are concerned, State Drug Control authorities should ensure that each manufacturer carried out proper stability studies and indicates the date of manufacture as well as a date of expiry, depending upon the result of the stability studies. The manufacturer will be responsible for the quality of the vitamin preparations until the date of expiry is crossed. No special storage conditions need be insisted upon for vitamin products for the present till the action set out at (a) above is completed.

(c) As regards antibiotics, manufacturers do not normally recommend any special storage conditions for these preparations. To make sure that antitbiotics keep well when stored in room temperature in the country, a collaborative study on the stability of antibiotic preparations should be undertaken by the Central Indian Pharmacopoeia Laboratory, Drugs Laboratory, Baroda and the

Analytical Laboratory of Maharashtra. A planned programme of sampling may be drawn up by these three laboratories and samples taken from different parts of the country may be examined. The samples should preferably be from stocks which are approaching the date of expiration. Such studies would serve to determine the storage conditions to be prescribed for preparations of antibiotics.

Item - 6

Suggestions to control the quality of sulphacetamide sodium solution (Eye Drops).

The Chairman stated that the subject had been brought for discussion as Sulphacetamide Sodium Eye Drops marketed in the country had been observed to develop colour and precipitation on storage. As a result of this, a number of samples of this preparation were reported to be not of standard quality and any action taken against the manufacturers of such preparations reported to be not of standard quality should be uniform throughout the country. The Committee, after discussion, recommended that :-

1. Such preparations where precipitation is observed should **not** be permitted to be marketed.

2. Efforts should be made to develop stable preparation of Sulphacetamide sodium solution for ophthalmic use and revised standards in the light of such experience should be included in the next edition of the I.P.

3. A provision may be made in the Drugs and Cosmetics Rules laying down that ophthalmic preparations of Sulphacetamide should bear a date of expiry which should be based on the stability studies conducted by each manufacturer.

Pending the measures enumerated above the Chairman advised that each State should keep a watch on the manufacturers who are marketing such preparations and report on their stability.

Item - 7

Question whether pharmacopoeial preparations should be permitted to be marketed as patent or proprietory medicines with slightly different composition.

The Chairman stated that in the last Drugs Consultative Committee meeting held in Cochin questions relating to the screening of the compositions of patent or proprietory medicines and uniformity of policy in regard to the manufacture of pharmacopoeial formulations in different strength were discussed. As a sequence of those discussions, the question whether a preparation which is marketed with a composition different from that given in the pharmacopoeia should be permitted to be manufactured as a patent or proprietory was discussed by the Committee. The Chairman felt that if this were permitted there would be a plethora of preparations containing the active ingredients in quantities far below the minimum therapeutic or prophylactic dose making it difficult for the Drug Control authorities to keep a check on their therapeutic efficacy.

After discussion, the Committee decided that patent or Proprietory medicines which conform to the pharmacopoeial formula should comply strictly with the composition given in the pharmacopoeia. Preparations like Codopyrine, Depryrine etc. which contain the same active ingredients as pharmacopoeial formulations, it was further agreed, should not be allowed to be marketed unless their formula is revised and made to conform to the pharmacopoeial formula.

Item - 8

Question whether a preparation containing combination of both Allopathic and Ayurvedic medicines can be considered as new drug and its approval is required by the Drugs Controller (India) under Rule 69(B) of the Drug and Cosmetics Rules,

The Chairman stated that there are a large number of preparations moving in the market which contain both Ayurvedic and allopathic ingredients. As such combinations do not fall within the purview of the definition of the term "Ayurvedic drug" in the Act, the question whether such medicines should be considered as "New Drugs" and whether approval of the Licensing Authority under rule 21 would be required for these preparations needs to be considered.

After discussion, the Committee decided that manufacturers who desire to introduce new combinations of Ayurvedic and Allopathic ingredients should be advised to get them approved as "New Drugs" by the Licensing Authority

mentioned in Rule 21 of the Drugs and Cosmetics Rules. As for similar combinations which are already in the market, the Committee felt that it may not be possible to reopen the cases and ask the manufacturers to get them approved as "New Drugs" at this stage. In such cases, the State Drug Control Authorities should ensure that the ingredients used are of standard quality. the manufacturers of such preparations should also be asked to evolve methods for standardization of such combinations.

Item - 9

Consideration of the scale of sampling of condoms that may be adopted by the Drugs Inspectors for testing from (1) the premises of manufacturers and (2) the premises of dealers.

The Chairman explained that condoms are not permitted to be imported under the current Import Trade Control Policy. However, substantial imports of condoms are expected to be received by the Family Planning Department of the Government of India under the U.S. AID Scheme and from Japan. Condoms are also indigenously manufactured by M/s. Hindustan Latex Limited in Kerala and M/s. London Rubber Company in Madras.

Regarding the quality of condoms imported on behalf of the Family Planning Department, arrangements have been made for the testing of samples of condoms either in the country of manufacture as in the case of Japan or at the point of entry when imports are made. The State Drug Control authorities of Kerala and Madras have been requested to keep a running check on the quality of the indigenously manufactured condoms.

The question that has now to be examined is the procedure for sampling that should be adopted if complaints are received from individuals that the quality of condoms used by them is not satisfactory. The fact that the minimum sample size for condoms is 144 pieces makes it all the more difficult for the State Drug Control authorities to take any action especially as 144 pieces may not be available. After discussion, it was agreed that the following action should be taken :-

(a) In the event of any complaint about quality of condoms State Drug Control authorities may take, samples from the distribution points and send them for test. If adequate number of samples is not available at such centres, the available stock should be made use of for purposes of test. The test report if adverse, should be further examined in relation to the quality of the bulk stock of the batch in question that will be available with the Government depots or manufacturers.

(b) Apart from checking the quality of condoms at the ports, a frequent check on the quality of the stocks maintained by Government in their depots should also be made. The Central Drugs Inspectorate should be entrusted with this task and samples should be taken by them from the storages depots of the Family Planning Department.

(c) Similar checks should be exercised on the quality of the condoms manufactured indigenously in the country. The assistance of the Drugs Controller Kerala and Madras may be sought in locating the stocks of condoms manufactured and distributed by Hindustan Latex Limited and London Rubber Company.

Item - 10

Question as to what combination of Sulpha drugs should be allowed to manufacture sulpha three tabs.

The Chairman stated that different types of "Triple Sulpha" preparations were being marketed in the country and there was need for uniformity of approach regarding their composition. The I.P., he added has no monograph of mixed sulphas while U.S.P. XVII includes a monograph under the description "Trisulphas Pyrimidines tablets" which contain sulphadiazine, sulphamerazine and sulphadimidine in equal parts.

The Director, Drugs Control Administration, Gujarat stated that Sulphanilamide should not be permitted as an ingredient of any formulation of 'Trisulpha' tablets. He further stated that before permitting any formulation, it should be subjected to trials and tests for efficacy and toxicity.

After discussion it was decided that combinations of trisulphas manufactured in the country should conform to the specifications prescribed in U.S.P. XVII or N.F. XII. U.S.A. Any other combinations should be deemed to be a "New Drug".

Item - 11

Review of the types of records and registers that should be maintained by the wholesale and retail dealers under the provisions of the Drugs and Cosmetics Rules - Recommendations of the Mukhopadhyay Committee.

The Committee considered the suggestion received from the State Drugs Controllers for the maintenance of records and registers by drug dealers. It was felt that the existing Rules are comprehensive enough and that the dealers have also not asked for any change in the Rules. The suggestion made by the Director, Drugs Control Administration, Gujarat that the wholesale dealers need not mention their names and the address in the cash memos of the licensee to whom drugs are supplied on conditions that a list of licensed dealers to whom supplies are made is maintained by him was agreed to. This procedure it was agreed should be adopted by the other States also.

Item - 12

Redressing of soiled cartons/labels on bottles of Drugs and Cosmetics.

The Committee considered the question whether redressing of soiled cartons or bottles of drugs and cosmetics with new labels should be permitted at the distribution centres by wholesalers or stockists of manufacturer. Since change of label constituted 'manufacture' and since such activity on unlicensed premises may give rise to legal complications, apart from providing scope for substitutions, it was decided that labelling of soiled cartons and bottles should be permitted to be carried out only by the manufacturers on their premises.

Item - 13

Consideration of the suggestion received from the Pesticides Association of India that insecticidal formulations which are marked for agricultural use

may be exempted from the provisions of the Drugs and Cosmetics Act.

The Committee considered the request received from the Pesticides Association of India that the insecticidal formulations which are marketed exclusively for agricultural use should be exempted from the provisions of the Drugs and Cosmetics Act. It was felt that since DDT, BHC, Dioldrin and pyrethrine are also used for public health purposes, it would not be possible to make any distinction between the public health use and use for agricultural purposes. The Committee agreed that Licences for manufacture of these insecticides and their formulations should be insisted upon.

Item - 14

Labelling requirements of Cosmetics - Showing the mode of labelling of the Batch Number on packings.

The question of showing the Batch Number and the manufacturing licence number on the labels of cosmetics was discussed. The Members pointed out that although the batch number is shown on the labels of cosmetics it becomes difficult for the Drug Control Authorities to identify it as only a mere number is displayed and there is no distinguishing abbreviation such as "M" Licence No. ", "Manufacturing Licence" etc." The Committee agreed that the batch number should be preceded by the Letter "B".

The Committee was informed that Govt, do not consider it necessary to provide that the manufacturing licence number of manufacturers of Cosmetics should be shown on the label. The Committee was of the view that when manufacturers of cosmetics can show the excise licence number on the label, there should be no difficulty in their displaying the manufacturing licence number also. It was strongly reiterated by the Committee that the manufacturing licence number should be shown on the labels of cosmetics and it would be enough if the manufacturing licence number were preceded by the letter 'M'.

Item - 15

Proposal to ban the manufacture and marketing of topical preparations

of antibiotics, Sulpha drugs etc.

The Chairman stated that following the recommendations of the Essential Drugs Committee that topical preparations of antibiotics, sulpha drugs are not essential and should be discouraged the question has been raised by some States whether such preparations should be banned. He observed that under the existing provisions of the Drugs and Cosmetics Act, there was no provision for banning the manufacture of such preparations. Shri Patel stated that if such preparations have been proved to be harmful, there should be no hesitation in banning them. The Committee agreed that till such time the Act was amended, manufacturers should be prevailed upon and discouraged to market such preparations. In the case of new manufacturing units, the sponsoring authorities in the States should not recommend to the Import Trade Control authorities the import of raw materials for such preparations.

Item - 16

Provision may be made in rule 139(2) to provide an independent premises specially reserved for manufacturing cosmetics similar to the provision in respect of Homoeopathic preparations under Rule 85 F(4).

The Committee agreed that the manufacturing premises in respect of cosmetics should be distinctly separate from the premises used for residential purposes and that a provision similar to sub-rule (4) of Rule 85 F should be introduced for cosmetics.

Item - 17

Rule 62 may be amended suitably making it compulsory for a person to obtain a licence for godown premises.

The Drugs Controller, Mysore explained that the suggestion had been brought for consideration of the committee in the context of a judgment delivered by a Mysore Court to the effect that a godown from where no sale is effected is not required to be licensed. Shri Sane stated that there was a Maharashtra

High Court Judgment on the subject which might be helpful to Mysore and agreed to send a copy of it.

Item - 18

Suggestion to amend Para 10 of the Drugs Prices (Display and Control) Order 1966 to empower the Investigating Officer to seize Cash-bills, invoices etc. for taking any specific action against the offender.

The Chairman explained that the Drugs Controller, Mysore desired to know whether Para 10 of the Drugs prices (Display and Control) Order 1966 empowerd the investigating officer to seize cash bills, invoices etc. for taking any specific action against the offender. The question, he added, had been referred to the Ministry of Law and their opinion will be communicated to all the State Drugs Controllers.

Item - 19

Question whether validity of the provisions of Sec.22 is questionable when read with sub-section 21(2) in the light of the meaning of the word 'prescribe' in Section 3.

The Committee felt that section 22 did not appear to be invalid even though sub-section (2) of section 21 states that the powers to be exercised or performed by Inspectors shall be prescribed by rules. Dr. Sarker was however, requested to obtain legal opinion, if necessary. In case there was need to make the powers of the Drugs Inspectors more specific or broad-based, requisite proposals could be forwarded for consideration when the Drugs Act is amended next time.

Item - 20

Clarification regarding the control of the Controlling Authority over the ex-officio Inspectors under the Drugs and Cosmetics Rules.

The Committee discussed this question and came to the conclusion that the ex-officio Inspectors appointed in terms of the third proviso to rule 49 will

be subject to the control of the Controlling Authority mentioned under Rule 50 of the Drugs and Cosmetics Rules.

Item - 21

Specific provisions should be made in the rules for production and quality control of tablets claimed to have delayed, repeat and sustained release action.

The Committee, after discussion, agreed, that tablets with delayed action or with claims for sustained release should be considered as 'New Drugs' and manufacturers of such preparations should be advised to obtain the clearance for such preparations from the Licensing Authority mentioned under Rule 21 of the Drugs and Cosmetics Rules.

Item - 22

Suggestion to authorise the Drugs Inspectors to exercise the power of police officer in Section 57 of the CRPC Act 1898 for the purpose of ascertaining the correct names and addresses of the person in possession of misbranded and adulterated drugs and from whom sample of drug is collected or the drugs is seized.

The Committee discussed the suggestion and come to the conclusion that the powers already vested in the Drugs Inspectors are wide enough and there was no need to provide any additional powers to the Drugs Inspectors for the purpose.

Item - 23

Provision should be made to lay down fees for inspection of establishments manufacturing Homoeopathic drugs, cosmetics and repacking pharmaceutical drugs.

The Committee agreed to the suggestion made by the Gujarat Drug Control Administration, that a provision may be introduced in the Drugs Rules for an inspection fee for inspection of the manufacturing premises engaged in the

manufacture of Homoeopathic medicines and cosmetics and that the scale of inspection fee for this purpose should be the same as has been laid down for repackers.

Item - 24 & 25

Provision may be made in the Drugs and Cosmetics Act providing punishment for contravention of Section 24 of the said Act.

Penal provision may be made for contravention of provisions to rule 54A for disposal of stock of drugs in respect of which prohibitory order is issued in a manner other than by way of sale or distribution i.e. by destruction.

The Chairman stated that amendments to the Drugs and Cosmetics Act cannot be made frequently and in a piecemeal manner. He promised that the suggestions made by the Director, Drugs Control Administration, Gujarat will be borne in mind when the Act is amended next time.

Item - 26

Suggestion to amend Section 18A read with Section 23(4) (iii) and 25(2) of the Drugs and Cosmetics Act so as to provide an opportunity to the Drugs Inspectors to examine the test report or sample in respect of sub-standard drugs manufactured by the manufacturers.

Shri Patel pointed out that as per the provisions of Section 18-A read with Sections 23(4) (iii) and 25 (2) of the Drugs and Cosmetics Act, the test report on a sample of a drug reported on as adverse is required to be sent to the dealer from whom the drug has been purchased by the dealer from whom the sample is drawn and not to the manufacturer. He felt that in such cases, the manufacturer should be given an opportunity to examine the test report.

Shri Sane pointed out that a provision exists under the Provision of Food Adulteration Act for sending, under similar circumstances, a copy of the test report to the manufacturer. The Committee recommended that a similar provision may also be introduced in the Drugs and Cosmetics Act when it is amended next time.

Item - 27

Consideration of the question of introducing a provision in rule 142 for maintaining records of cosmetics by the manufacturer.

The suggestion made by the Director, Drugs Control Administration, Gujarat that records of manufacture should be maintained in respect of cosmetics by the manufacturers was agreed to by the Committee. The Director, Drugs Control Administration, Gujarat agreed to forward for further examination a draft of the proforma for maintenance of these records.

Item - 28

Consideration of the question of amending the Rule 108 of the Drugs and Cosmetics Rules to include plastic containers also for filling of parenteral preparations.

The Committee decided that Rule 108 of the Drugs and Cosmetics Rules should be amended so as to permit the use of plastic containers for parenteral preparations.

Item - 29

Provision may be made for granting permission to manufacture additional items for repacking of drugs other than those in Schedule C & C1.

Shri Patel informed the Committee that under the existing Rule 69(5) and Form - 25 of the Drugs and Cosmetics Rules, a regular manufacturer of a drug need not obtain permission from the Licensing Authority for repacking drugs other than Schedule C and C1. The Committee considered such a provision is necessary and recommended that Rule 69(5) and Form-25 should be amended in such a manner as to make it mandatory on the part of the licensee to have the names of drugs which are repacked to be endorsed on the licence in Form-25.

Item - 30

Consideration of the question of amending the exemption provision made in respect of contraceptives and disinfectants in Schedule K.

Shri Patel explained that in terms of the exemptions provided for in entries 12 and 14 of Schedule K to the Drugs and Cosmetics Rules, dealers in disinfectants and contraceptives are exempted from the provisions of Chapter IV of the Act which require them to be covered by a sale licence. It has been brought to the notice of Gujarat Drugs Control Administration that dealers had been selling time-barred, contraceptives and disinfectant fluids which have crossed the date of expiry shown on the label.

The Committee, after discussion, recommended that the relevant entries in Schedule K of the Drugs Rules should be amended so as to debar dealers from stocking or selling drugs which have become time-expired.

Item - 31

Proposal to amend Rule 2(g) of the Drugs and Cosmetics Rules, so as to bring the sale to a manufacture by a wholesale dealers for use in the manufacture of drugs, within the purview of the definition contained therein.

Item - 32

Question as to what action could be taken in cases of parenteral preparation containing foreign particles.

Item - 33

Consideration of the question whether loose sale of capsules and tablets from bulk packings is permissible.

Item - 34

Suggestion to lay down suitable guidelines for inspection of hospitals and pharmacies.

Since the Drugs Controller, Tamil Nadu did not attend the meeting and since the background against which the subjects had been brought for discussion was not known, the Committee did not consider the above items.

Item - 35

Consideration of the necessity of issue licences to representatives of distributors who supply drugs to whole salers and retailers.

The Committee decided that there was no necessity to insist on a sale licence to be taken by the sales representatives of manufacturers or their distributors.

Item - 36

Provision may be made under Rule making it compulsory for dealers to record batch No. of drugs other than Schedule C in Cash and Credit Memo.

The Chairman recalled that the rules relating to maintenance of records and registers by dealers had been specially examined by a sub-committee consisting of State Drugs Control authorities in consultation with the representatives from the drug trade and were amended recently. The idea behind such examination and consultations was that while records and registers which are essential from the quality control angle should be insisted upon. Dealers should be assisted by doing away with those records which entailed unnecessary and unproductive clerical labour. One of the agreements reached as a result of these discussions was that records of retail sale of drugs not covered by Schedules C & E may be maintained in Cash Memo and that the batch number need not be recorded in the Cash Memo. The Committee agreed in the circumstances that it may not be worth-while re-opening the whole issue.

Item - 37

Suggestion that perfumes applied or sprinkled on clothes should also be covered under definition of Section 3(aaa).

The definition of the term 'cosmetics' as given in the Drugs and Cosmetics Act included articles which are intended to be rubbed, poured, sprinkled or sprayed as or introduced into otherwise applied to the human body or any part thereof. In view of this definition, the Committee felt that it would not be possible to

control perfumes which are applied to or sprinkled on clothes and not on the human body.

Item - 38

Provision should be made in the Act requiring the manufacturers to disclose the particulars of the source from where they obtain the raw materials.

The Committee was of the view that it may not be necessary to lay down a provision in the Drugs Rules making it mandatory on the part of manufacturers to disclose the particulars of the source from where they obtain the raw materials. It is necessary however that the raw materials should be of standard quality and for this purpose forms for maintenance of records of drugs have already been laid down in the Drugs and Cosmetics Rules.

Item - 39

Clarification whether Rule 62(A)(b) is applicable for issue of a whole-sale restricted licences to itinerant vendors.

Shri Patel informed the Committee that the practice followed in his State was to grant restricted liecences so that drugs could be distributed in mobile vans in the remote parts of the State. The Committee agreed that this procedure could also be followed in Madhya Pradesh if found suitable.

Item - 40

(a) Suggestion that a condition may be added in Form 20-D making it compulsory to sell the medicines to licensed dealers only on the lines of similar condition in licence Form 20-B.

(b) Suggestion that a condition may be added in Form 25-C making it compulsory for manufacturer to sell medicines only to licensed dealers on similar lines of licence Form 25.

Item - 41

Provision should be made in Rules making it compulsory for dealers or

manufacturers to disclose the constitution of their firms to the licensing authority of other States on demand.

Since no representative from the Drugs Control Administration in Madhya Pradesh was present, the Committee could not consider these items.

Item - 42

De-addiction and Hospitalisation of Opium addicts in all the States as in Assam State.

The Drugs Controller, Punjab, desired to know the methods adopted for treatment of addicts, particularly hospitalised treatment of opium addicts in the country. The Chairman stated that the subject did not fall within the purview of the Committee and that, however, to the best of his knowledge, Gujarat had made considerable studies in this field. Shri Patel informed the Committee that one Dr. Patel in the State Civil Hospital has been treating addiction cases with Methadone and this method had evoked keen interest in the WHO and other circles.

The Chairman stated that the WHO has published pamphlets on modern methods of treatment of drugs addicts including addicts to narcotics and that if the states felt that the subject should be given a greater degree of attention on all-India basis they could write to the D.G.H.S. It may be possible for the latter to convene a meeting of the representatives from the States, the WHO and the I.C.M.R. The representatives from the Punjab and certain other States were of the view that the hitherto conventional methods used for the treatment of addicts to narcotics and other drugs needed to be changed in the light of the recent developments in this field and that the States expected advice and guidance from the Centre.

Item - 43

Mis-use of barbiturates - Steps to be taken by different States to check its mis-use.

The representative from Punjab stated that in his State the misuse of barbiturates for non-medicinal use has assumed an alarming proportion and unless some positive measures were taken to control the import, manufacture, sale and distribution of barbiturate the position might aggrevate further. Since Punjab was a border State and also provided recruiting material to the army, the problem has assumed severe significance. He also said that there were reports that in Pakistan addiction to hallucinogen such as L.S.D. was on the increase and that there was every possibility of such dangerous material being smuggled into Punjab.

The Chairman informed the Committee that reports had been received earlier about the large scale misuse of barbiturate in Punjab. The Assistant Drugs Controller (India) North Zone and senior officer from the C.B.I. had made an on-the-spot study and given their recommendations. The report is now under consideration and a conference with the Director of Health, Punjab, C.B.I., etc. is being arranged. The Committee discussed the subject at length and made the following recommendations :-

1. Import of barbiturates should not be allowed to Established Importers as the latter serve as a source of supply.

2. Manufacture of barbiturates should be restricted by the State Drugs Control authorities to a limited number of those whose bonafides are established. The quantitive production should also be restricted to the minimum. The maintenance of proper records of distribution by manufacturers should be enforced stringently and inspected frequently. The co-operation of the excise authorities should be sought in enforcing these regulatory measures.

3. Firms which were suspected of selling or distributing barbiturates in contravention of the provisions of the Drugs and Cosmetics Act should be subjected to frequent inspection by Drugs Inspectors and plain clothed police.

4. It would be necessary for the concerned states to examine the identify the areas where misuse of barbiturates is a real problem. Apart from certain dealers indulging in purchases of barbiturates from unauthorised sources and dealing in them insisting upon prescription and without maintaining records of sale a certain section of the medical profession in clear disregard of their

professional ethics have been conniving with the dealers by providing bogus prescriptions for barbiturates for addicts. The Director of Health Services, Punjab has been requested to arrange for a top level conference with the local police, excise authorites, medical associations etc. which the Central Drugs Control Organisation and the C.B.I. would be glad to attend.

It was also mentioned by some members that in certain states Ayurvedic and Unani practitioners of the systems of medicines have been considered as 'Registered Medical Practitioners' with the result that the scope for misuse has been increased. Medical practitioners who had not undergone any academic training in modern drugs or who do not have any background knowledge of pharmacology and therapeutics should not be allowed to prescribe barbiturates and other dangerous drugs.

An observation was made that Delhi manufacturers were mainly responsible for the supply of barbiturate preparations to the Punjab and Haryana and that restriction of their production in Delhi, vigilant check on their distribution by Delhi manufacturers at the points of wholesale supply in other States and timely communication of the quantities distributed could lead to better controls in the States of consumption. Punjab, it was stated, had not permitted the manufacture of barbiturates. The Drugs Controller, Delhi, assured that he would hold discussions with the manufacturers of barbiturates in his area to evolve ways and means of minimizing production of barbiturates. He would also examine how best information regarding the distribution of barbiturates to other States could be conveyed.

Shri B.V. Patel, Director, Drugs Control Administration, Gujarat brought to the notice of the Committee that measures for keeping a rigid control over the production and distribution of narcotic drugs, barbiturates had been recommended earlier by a sub-committee of the Drugs Technical Advisory Board with late Dr. H.R. Nanji as convener. He mentioned that if these recommendations could be implemented without waiting for a revision of the Schedules E,G,H and L to the Drugs and Cosmetics Rules, positive results can be expected in preventing the misuse of barbiturates. The Chairman assured the Committee that he would examine Dr. Nanji's report and take necessary action.

Item - 44

Provision should be made to the effect that capsules are made available either in strip packs or in a quantity of not more than 4 capsules in a vial for minimising the chances of their misbranding or adulteration.

The suggestion of the Drugs Controller, Haryana, was considered. The Chairman stated that in the context of shortage of strip-packing machines and other packing mateials such as metal foil etc. in the country, it may be difficult to make it mandatory to have capsules strip-packed. Manufacturers, he said, are becoming increasingly conscious of the fact that it is in their own interests to adopt strip-packings for capsules and tablets and are resorting to such packings. The State Drugs Control authorities should continue to bring pressure on manufacturers to adopt strip-packings or pilfer proof packing for their drugs.

Item - 45

Suggestion to lay down details of the equipment, space laboratory equipment and the staff to be employed for the manufacture of homoeopathic medicines and mother Tinctures under Rule 85 E and 85 H of the Drugs and Cosmetics Rules.

The suggestion of the Drugs Controller, Haryana, that details of the equip ment, space, laboratory equipment and the staff to be employed by the manufacturer of Homoeopathic Medicines and Tinctures should be laid down in the Drugs Rules was agreed to in principle. However, the Committee felt that it would be necessary to inspect the premises of leading manufacturers of Homeopathic medicines in this country to draw up a list of these requirements before these are incorporated in the form of Rules under the Drugs and Cosmetics Rules. The following Sub-Committee was constituted for this purpose.

1.	Shri B.V. Patel	Chairman
2.	Dr. B.B. Sarker	Member
3.	Dr. Chopra	Member
4.	Dr. K.G. Saxena, Adv. in Homoeopathy in the Ministry of Health	Member

5.	Shri M.K. Rangnekar	Member
6.	Shri S.H. Merchant	Member Secretaries
7.	Dr. V.A. Moghe	

Item - 46

Consideration of the question as to whether Pharmaceutical specialities in Aerosol form should be considered as 'New Drug'.

The proposal from the Drugs Controller Administration Maharashtra was discussed. Shri Patel informed the Committee that there was little danger from the propellent gas whose properties are sufficiently known at present and that the co-solvents which are used should be examined for potential hazards, if any. The Committee, after discussion recommended that pharmaceutical specialities in aerosol form involving the use of metered out dose should be considered as 'New Drug' as clinical aspects regarding their satefy and efficacy will have to be assessed.

Item - 47

Consideration of the question of specifying the amount of sample to be taken for sterility test and percentage of containers for fungi test for transfusions.

The Committee recommended that the suggestion made by the Director, Drugs Control Administration, Maharashtra may be taken into consideration before finalising the draft amendments to Rules 118 of the Drugs and Cosmetics Rules relating to the sterility test.

Item - 48

Consideration of the question of amendment to the definition of the clause (2) of term 'disinfectants' as appearing in Drugs and Cosmetics Rules.

It was explained that the intention of the notification defining the term 'Disinfectant' was to control disinfectants fluids made from synthetic or naturally occuring substances and also those fluids which by virtue of their composition possesses disinfectant properties though the latter may be sold as deodarants.

For this purpose it was necessary to have the word 'or' between these two types of disinfectants fluids. In view of this clarification it was decided not to amend the notification which has been published.

It was brought to the notice of the Committee that large-scale users like the railways, Government hospitals etc. have been indenting for deodarants while they actually needed disinfectants fluids. The deodarants now marketed are mainly designed to circumvent the provisions of the Drugs and Cosmetics Rules which regulate the standards of disinfectant fluids and do not have any disinfectant properties. The Chairman suggested that the Drugs Control authorities at the State and Central level should recommend to State A.M.Os. and other indenting authorities that for purposes of disinfection of hospitals, disinfectant fluids conforming to the specifications laid down in the Drug Rules should be used and that the so-called deodarants would not serve the purpose.

Item - 49

Consideration of the question of determining which would be deemed to be a new drug and procedure to be followed in respect of Radioactive drugs by Bhabha Atomic Research Centre on behalf of other Institution.

Shri Sane raised two points :-

(a) How long should radioactive drugs which are not in the pharmacopoeia be treated as new drugs; and

(b) the procedure that should be followed in clearing new radioactive drugs manufactured by Bhabha Atomic Research Centre for investigation and clinical trials by other institutions and doctors.

Regarding (a), the Chairman stated that the radioactive drugs which are not in the pharmacopoeia will continue to be considered as new drugs till they are finally absorbed by the pharmacopoeias. As for the drugs required for investigation and trials by institutes and other doctors, it was decided that the Bhabha Atomic Research Centre should give the names of the radioactive drugs which are cleared by Radiation Medical Centre together with the names of the doctors etc. who desire to conduct clinical trials so that test licence could be issued

after ascertaining the competence of the doctors for the use of such drugs and the facilities available with them for such trials.

Item - 50

Consideration of the question of action to be taken in respect of some drugs reported to be not of standard quality and consideration of the question of fixing sampling programme by Drugs Controller (India).

(i) Parenteral preparations found to be not of standard quality on account of suspended matter.

Shri Sane stated that a large number of samples of parenteral drugs in the State are reported to be not of standard quality on the ground that they contain suspended matter. He added that the presence of suspended matter may not due to deterioration of the active ingredients but also to various other factors such as the quality of the glass of the container, the rubber bungs, variations in the quality of raw-materials etc. He desired that the question should be discussed so that a uniform policy in regard to the action to be taken in such cases could be decided upon. He added for the information of the Committee that the practice followed in his State was to order the withdrawal of the preparations in case the controlled samples retained by the manufacturers were also found to contain suspended matter.

Dr. Chopra stated that the intensity of shock and anger that the medical practitioner and the consumer feel when they see suspended matter in injections should not be ignored while discussing what action should be taken in such cases. Shri Patel stated that two aspects will have to be considered namely, (a) how to minimise the incidence of the suspended matter, and (b) the action that should be taken in regard to the preparations found to contain particulate matter. He was of the opinion that withdrawal of the defective preparation should be carried out in all cases.

Shri Patel also indicated that the Baroda Analytical Laboratory had carried out studies on the nature of suspended matter encountered in injectable preparations and tranfusion solutions. The contaminants, in most cases, had leaked from

rubber bungs. A drug manufacturer in Gujarat had organised research studies for developing a protective coating for rubber bungs and if successful the problem of suspended particles in tranfusion solutions and vials could be reduced to the minimum. He recommended that analytical laboratories would do well to study the nature of the contaminant by centrifuging the solutions and identifying the matter. "The particle Atlas" published could serve as useful guide for this purpose. Such studies could help us to remedy the basic defects.

The Chairman observed that parenteral preparations reported to contain suspended matter should not be permitted to be sold merely because the record samples did not show any such defect. The feelings of the doctor and the patient have also to be borne in mind. He, however, admitted that though it was not entirely possible to eliminate suspended matter in the absence of quality control measures in the glass and rubber industry.

Shri Sane stated that in Maharashtra they were encouraging manufacturers to pool their requirements of glass containers and rubber bungs so that drug manufacturers could bargain for better quality products.

After discussion, the Committee recommended the following steps :-

(a) State Drug Control authorities should advise drug manufacturers to pool their requirements of glass containers and rubber bungs so that the former may be in a bargaining position for obtaining quality Products;

(b) Drug Control authorities at the Central and State level should bring manufacture of glass containers and rubber bungs into more intimate contact with the consumers in the drug industry so that the requirements of drug manufacturers and the disabilities suffered by the manufacturers of packing material could be mutually appreciated; and

(c) All Analysts should adopt a uniform method for the detection of particulate matter in parenteral preparations namely, examination of the preparations by the naked eye in daylight and when analysts declare samples to contain suspended matter, mere examination of the record samples maintained by manufacturers will not be sufficient. Trade samples from the depots

or distributing manufacturers or from dealers should be re-examined. If full information is supplied, the Central Zonal Drug Control Organisation would try to examine stocks of the product complained of in their areas and send telegraphic reports so that withdrawal of the batch could be carried out.

(ii) **Standards for Absorbent Cotton Wool.**

The suggestion made by the Drugs Control Administration Maharashtra regarding the change in the I.P. specifications in respect of Absorbent Cotton Wool was discussed.

The Chairman stated that a number of manufacturers of Absorbent Cotton Wool use cotton waste as basic material for manufacture, it was difficult for them to comply with the I.P. specifications for Absorbent Cotton Wool. He suggested that the standards drawn up by the I.S.I. should be adopted, as they represented the greatest common measure of agreement among the consumers.

The Director, Drugs Control Administration, Gujarat stated that those manufacturers using Bengal Desi Cotton did not find any difficulty to manufacture Absorbent Cotton Wool conforming to the I.S.I. specifications. However, during the processing operations, the basic qualities of cotton were likely to be affected drastically.

The Committee agreed to the following lines of action to be taken :-

(a) Standards for wool cotton absorbent should be drawn up on the basis of Bengal Desi Cotton and the discussions at the I.S.I. which had brought together almost all consumer interests.

(b) A survey should be made of the absorbent wool cotton industry in the country as to whether they use Bengal Desi Cotton or Cotton waste as the starting material ; and

(c) Dr. P.K. Gupta, Zonal Officer in the Southern Zone would consult the Textile Research Centre in Coimbatore and the Institute of Technology at Madras for a suitable method of manufacture of wool cotton absorbent from

Bengal Desi Cotton. Similar enquiries may be made by the State Drug Control authorities, if possible.

(iii) **Standards for Surgical Gauze**

The suggestion of the Director, Drugs Control Administration, Gujarat, that the I.S.I. standards for surgical gauze should be adopted for the purpose of the Drugs Act was agreed to by the Committee.

(iv & v) Question of fixing a limit for sulphanilamide in the sulphacetamide Eye Drops.

Testing of Condoms.

Both these items had been discussed earlier vide Agenda Item No.9

Item - 51

Consideration of the question of making a provision in Drugs and Cosmetics Rules to the effect that the Drugs Stores should be owned by a Registered Pharmacist only.

The Committee considered the question of making a provision in the Drugs and Cosmetics Rules to the effect that drug stores should be owned exclusively by Registered pharmacists. It was felt that though it would be desirable to lay down such a provision it was premature to take any such action.

Item - 52

Consideration of the question of amending existing labelling provisions for cosmetics.

This subject had been considered earlier vide the Agenda Item No.14.

Item - 53

Consideration of the question of laying down minimum conditions for grant of a licence to manufacture cosmetics.

The suggestion made by the Drugs Control Administration, Maharashtra for laying down minimum conditions for the grant of a licence for the manufacture of cosmetics was discussed by the Committee and it was decided to accept them as guidelines for the present. (Annexure - II)

Item - 54

Relaxation of qualifications of Inspectors under rule 49 of the Drugs Rules for sale premises.

Initiating the subject, Shri Sane stated that the proposal had been made mainly to overcome the shortage of graduate pharmacists. Besides, the basic technical knowledge acquired by a diploma holder would be more than adequate for inspection of sales establishments.

The Chairman stated that two aspects needed special consideration. While the proposal has been mooted on the ground that graduate pharmacists are not available in adequate numbers for appointment as Inspectors, the picture presented by States such as West Bengal, Mysore and Madras is that Pharmacy graduates in those states have not been able to secure jobs. Secondly, the consequences of appointing Diploma holders as Inspectors on a lower salary scale as compared to graduates may not be healthy especially in matters relating to professional integrity which is vital in the field of Drugs Control.

Shri Patel said that if Diploma Holders in Pharmacy were appointed as Drug Inspectors, it would not be possible for the State Government to declare them as Gazetted Officers especially as their pay-scale was bound to be lower than that for Inspectors with graduate qualifications. This would lead to undesirable differentiation in the same profession and cause in efficiency. Besides, he added that such Inspectors will lanquish in the development for want of avenues of future promotion which would create serious problems to the Organisation.

The Committee after discussion felt that it would not be desirable to appoint Diploma holders in Pharmacy as Drug Inspectors.

Item - 55

Control over the manufacture and sale of Stains and Chemical Agents used as Diagnostic Agents under the Drugs and Cosmetics Act.

The question whether microscopic reagents, Stains and diagnostic agents should be controlled under the provisions of Drugs and Cosmetics Act was discussed. It was felt that while legally there may be no objection in controlling such substances under the Act, the question as to how best their standards could be regulated from the practical point of view needed examination.

The Chairman stated that the decision to control stains and diagnostic agents was taken mainly because complaints regarding their inadequate performance had been received. Besides, the reaction of the public if diagnostic reagents such as Benedix solution, teststrips for determining the content of sugar in urine do not give satisfactory results must not be ignored.

After discussion it was agreed that control for the present should be limited to very essential diagnostic reagents and stains which are commonly used by the hospital or the general public, sera etc. used for determination of blood groups, preparations for oral or internal use for diagnosis of the diseases etc. The Committee further decided that the Deputy Drugs Controller (India), Central Drugs Control Organisation (West Zone) should discuss the subject further with the Drug Control authorities in Maharashtra and Gujarat and draw up a list of reagents to be regulated and compile standards for them.

PART II

ANNEXURES TO THE MEETINGS

ANNEXURE - I

STATEMENT SHOWING THE ACTION TAKEN ON THE MINUTES OF THE TWELFTH MEETING OF THE DRUGS CONSULTATIVE COMMITTEE HELD AT COCHIN ON THE 19TH AND 20TH SEPTEMBER, 1968.

Item No.2 of 13th D.C.C Meeting

Item No.	Recommendations of the Drugs Consultative Committee	Action taken
(1)	(2)	(3)
Agenda Item No.1 i) Staffing Patterns in States.	The Chairman pointed out that the Committee on Drugs Control had highlighted the deficiencies obtaining in Drug Control Administration in various States and it had also given the staffing pattern that should be followed by each State. Most of the States had not been able to rectify the deficiencies in their organisations and augment their organisation to the desired extent. The Chairman requested the members to write to him about the present staffing pattern and also the steps taken to augment their organisation. The difficulties that are encounter in expanding the Drug Control Departments to the level recommended in the report of the Committee on Drug Control may also be mentioned in this letter. The Central Organisation, he said, would seek the assistance of the Government of India, Ministry of Health, Family Planning and Urban Development to take up the matter with the State Governments.	The Drugs Control authorities of the states were requested to furnish the information regarding the present staffing pattern and also the steps taken to augment their organisation. The replies so far received reveal that some of the States have augmented their staff while others have put up their proposals to their respective Govts. One or two states have stated that due to financial stringency their proposals could not be considered favourably by their State Govts. but efforts are being made by them to expand their Drug Control Organisation.
ii) Corrections to be made in I.P. 1966.	The Chairman also dwelt on the need for correcting data supplied in the Indian Pharmacopoeia 1966 edition. He requested members, particularly the Drug Control authorities of Maharashtra, Gujarat and West Bengal where the industry was concentrated to get in touch with the drug manufacturers located in their respective States and to ascertain the corrections that need to be made in the I.P.1966.	The Drugs Control Authorities of States were requested vide this Dte. Letter No.53-18/68-D dt.22.1.69 to get in touch with the drug manufacturer located in their respective State and ascertain the corrections that are required to be made in the Indian Pharmacopoeia 66. The States which have forwarded the corrections to be made in I.P. 1966 have been referred to the Indian Pharmacopoeia Committee for its consideration.

(1)	(2)	(3)
Agenda Item - 2 Use of time expired drugs.	The action taken on the minutes of the eleventh meeting of the Drugs Consultative Committee was explained by the Chairman. Regarding the action taken on Item 1(v) about the use of time-expired drugs, the members stated that it would be more appropriate if the Government of India, Ministry of Health, F.P. and U.D. wrote to the States on this subject. The recommendation made by the Drugs Consultative Committee on this issue could be forwarded to the States for the guidance of their Administrative Medical Officers.	The recommendations of the Drugs Consultative Committee have been forwarded to the State Govts. by the Ministry of Health, F.P. & U.D. for information and necessary action.
Agenda Item - 3(a)		
Suggestion made by the Director, Drugs Control West Bengal that if medical Glucose is controlled under the Drugs and Cosmetics Act, medicinal lactose should also be treated on the same footing and that both could be broughtunder control if the word lactose is removed from the exemption clause.	The Committee considered the question whether 'Lactose' should be removed from the entry 10(ii) of Schedule 'K' wherein it has been described as an article of food as well as drug, on the same anology as 'Glucose'. Since Glucose for which no therapeutic claims are made is not considered as drug, the Committee recommended that 'Lactose' un deridentical conditions, should also not be considered as a drug. It was agreed that entry 10(ii) of Schedule 'K' should be amended suitably.	The proposal regarding deletion of the word 'Lactose' from the entry 10(ii) of the Schedule 'K' to the Drugs and Cosmetics Rules has been referred to by the Ministry of Health and Family Planning to the Drugs Technical Advisory Board for its consideration.
	The Chairman said that following the decision taken a rise in the prices of Glucose and Lactose could be expected. He however said that since Glucose was taken as a food supplement by invalids, it was necessary to make sure that the article sold in the market was of standard quality. Standards for Glucose had been laid down under the P.F.A. Act and these standards would be circulated to the State Drugs authorities who, in turn, could draw the attention of the authorities responsible for enforcing the quality of food items to those standards.	A copy of the standards for glucose prescribed under the Prevention of Food Adulteration Rules was sent to all State Drugs Control authorities under this Directorate Letter No.53-5 /68-D dt. 13.2.1969 for guidance. The standards for lactose have not yet been laid down under P.F.A. Act and the question of laying down standards for this item is under consideration of this Dte. as already communicated in the above letter

(1)	(2)	(3)
Agenda Item - 3(c) Consideration of the suggestion made by Dr D.Ghosh Director, Central Drugs Laboratory, Calcutta on the recommendations of the Drugs Consultative Committee regarding provision to be made under the Drugs and Cosmetics Act and Rules for the Government Analyst to give his opinion regarding the labelling of drugs and declare them to be misbranded whenever necessary.	The Committee, after discussion, recommended that :- a) the test report of the Government analyst should essentially comment on the fact whether the drug is of standard quality or not; b) and that actual comments on other aspects of the drug (such as labelling, net content, packing/container etc.) might be shown below as an 'Observation' or a 'Note' or N.B.' in such a manner as to leave it to the State enforcement authorities to draw their own conclusion from the facts set out as to whether the drug is 'misbranded' or not.	The decision taken at the Drugs Consultative Committee was conveyed to its members vide this Dte. Letter No.53-20/68-D dt. 23.1.1969 with a request to bring this decision to the notice of the Government Analysts in their respective States for necessary action.
Agenda Item -3(d) Suggestion made by West Bengal that the question of a suitable definition of the term 'Batch' in respect of medicinal gases may also be considered in the light of general manufacturing practices.	The Committee after discussion agreed that the production of medicinal gases in a week from one tank load should be considered as a "Batch" provided the tank was emptied every week. In case, however, the manufacture was a continuous process in which the tank was not unloaded after a week, a day's prodution might be considered as constituting a "Batch". The Director, Drugs Control Administration, Maharashtra stated that he had drawn up a list of tests that might	The draft amendment to Rule 96 giving the explanation to term 'Batch' relating to the various classes of drugs is under process. The term 'Batch' in respect of medicinal gases has also been included in this draft keeping in mind the guide lines given by the Drugs Consultative Committee. A note on tests to be conducted on medicinal gases drawn up by the

(1)	(2)	(3)
	be carried out on the medicinal gases and those might be helpful to other State Drugs Control authorities. The Chairman requested Shri Rangnekar to forward the information to the Central Organisation so that it could be circulated to all the State Drug Control authorities.	Director, Drugs Control Administration, Maharashtra was circulated to the State Drugs Control authorities under this Directorate Letter No.53-22/68-D dt. 18.6.1969 for guidance.
Agenda Item-3(e)(i)		
Amendment to rules 96 to 109 of the Drugs and Cosmetics Rules regarding particulars to be shown on ampoule lables-Recommendation of the Sub-Committee.	The recommendations of the Sub-Committee were agreed to by the Drugs Consultative Committee at its last meeting held at Cochin subject to the certain changes to be made in the draft amendments to rules suggested by the Sub-Committee.	The draft amendments as suggested by the Sub-Committee have been referred to by the Ministry of Health & F.P. & U.D. to the D.T.A.B. for its consideration.
Agenda Item-3(e)(ii)		
Consideration of the manner in which the date of expiry should be shown taking into account the present practice followed by some manufacturers of showing only the month and the year which leaves the trade in doubt whether the drugs are expected to retain their potency till the end of the month or till the beginning of the month.	The Committee was of the view that date of expiry should be given in terms of month and year. It would mean that the product is potent till the last date of the month. Further the date of expiry given as indicated above should be proceeded by the words "Expires".	The proposal has been referred to by the Ministry of Health, F.P. and U.D. to the D.T.A.B for its consideration.

(1)	(2)	(3)
Agenda Item-3(e)(iii)		
Consideration of the procedure that could be followed by manufacturers for indicating on the label that the drugs conform to the National Formulary Standards.	The Committee was of the view that if the words ('N.F.I.) are mentioned on the label, following the name of the drugs as given in the National Formulary it should be considered as the drug having been manufactured according to the formula given in N.F.I. and the necessary provision should be made in the rules, that when a preparation is labelled as (N.F.I), it shall not be necessary to give formula on the label.	The proposal has been referred to by the Ministry of Health and F.P. and U.D. to the D.T.A.B. for its consideration.
Agenda Item-3(e)(iv)		
The question of defining the term 'Compunding' and 'Dispensing' as suggested at the 10th Drugs Conference and the question whether experience of sale across the counter could be deemed to be adequate to consider a person as "qualified person under the Drugs and Cosmetics Rules.	Since Dispensing includes compounding it was not considered necessary to define the terms 'dispensing' and 'Compounding' separately. A new category of persons possessing the minimum academic qualification of S.S.C. or an equivalent examination and with an adequate knowledge of preparation of drugs, their action, stability, dosage, storage conditions and the different schedules under which the drugs are classified etc. should be permitted to sell prescription drugs other than habit forming drugs in original packing or in loose form.	The proposal has been referred to by the Ministry of Health and F.P. to the D.T.A.B. for its consideration.
Agenda Item No.4		
Consideration of the question of laying down guidelines for enforcement of rule 62(B)(2) and 64(2) of	The Chairman said that the existing rules 64 and 62(B) are not comprehensive and do not lay down proper guide lines for granting sale licence keeping in mind the limitations set out in them. He stated that the regulations followed in France, Goa, and Portugal for grant of sale	A note on the procedure adopted in France and Goa for the grant of sale licences on the basis of population was circulated to the Drugs Control authorities of the State vide this Dte.

(1)	(2)	(3)
Agenda Item No.13 Consideration of the question of licensing the manufacture and sale of Diagnostic agents and laying down standards for them.	During the discussion of this item the Committee had desired that it would be useful if the standards for diagnostic agents including stains and enzyme strips for diagnosis as might have been laid down by the Food and Drug Administration of U.S.A. and Canada are obtained and circulated to the State Drugs Control Authorities for their information.	This Directorate had addressed the Food and Drug Authorities of U.S.A. and Canada to furnish the list of diagnostic agents controlled by them under the purview of the Food, Drugs and Cosmetic Act along with the standards. Replies have been received from both the Administrations. The Food Drug Administration, U.S.A. have confirmed that diagnostic agents are subject to the jurisdiction of the Federal Food, Drugs and Cosmetics Act. However with the exception of antibiotic sensitivity dies in respect of which standards have been laid down they have no list of such diagnostic preparations. The Food Drug Directorate, Canada have informed that at present only diagnostic agents other than the one which are injected, swallowed by man or applied on human body, are not considerd to be drugs and consequently are not subject to their present legislation. However, it is expected that in some near future their legislation will be amended in such a way that these products will be covered by their Food and Drugs Act and Regulation. The above information was *communicated to all State Drugs Control authorities vide this Dte. Letter No.53-36/68-D dt. 6.5.1969.*

(1)	(2)	(3)
Agenda Item No.14 Consideration of the question whether manufacture of articles like if perfumery compounds, aromatic chemicals which are used as raw materials in other industries besides the Cosmetics industry should be required to be licensed under the Drugs and Cosmetics Act and Rules, treating them as components of cosmetics.	The Director Drugs Control Administration Maharashtra explained that in his State the practice had been that if an item was used in the manufacture of cosmetics as well as in other industries, no licence for its manufacture under Drugs Act was insisted upon. The Committee, recommended at that same procedure might be adopted by other States subject to the conditions that the item was not labelled as of "Cosmetic grade".	In view of certain comments received from the Director, Drugs Control Administration, Maharashtra the proposal will be discussed at the forth coming meeting of the Drugs Consultative Committee for suitable amendments of the minutes to be made under this item.
Agenda Item No.16(a) Question of amending Section 22(a) of the Drugs and Cosmetics Act to make specific provisions empowering an Inspector to inspect any premises where drugs are sold, stocked or exhibited for sale or distributed, similar to the one relating to manufacture which already exists.	Shri Patel explained that under Section 22 of the Drugs Act, 1940 there was no specific provision empowering the Inspector to inspect premises where drugs are sold or stocked or exhibited for sale or distribution similar to the one relating to manufacturing firms. When the Act did not vest the inspector with specific powers rule 51 cannot go beyond the scope of the provision of the Act. It was, therefore, necessary to amend Section 22 of the Act vesting the Inspector with the said powers. The Chairman stated that the view of the Law Ministry would be obtained as to whether rule 51 is in consonance with the parent provision in the Act.	The matter was referred to the Ministry of Law for their views as to whether Rule 51 is in consonance with the parent provision under Section 22 of the Act and whether it would be necessary to amend Section 22 of the Act by providing the necessary powers to the Inspectors to inspect the sale premises. The views of the Law Ministry are as below :- In the light of Section 22(1)(d) read with Clause (b), it cannot be said that rule 51 is not in consonance with the parent provisions of the Act as Sec.21

(1)	(2)	(3)
		(i)(d) states that the inspector may exercise such other power for carrying out the purposes of Chapter III or any rules made thereunder. The Ministry of Law, however have stated that the element of doubt which is not unlikely to arise in this regard may be cleared by making an explicity provision. When the Act is amended next time opportunity will be availed of to include an explicity provision under Section 22 by providing the necessary powers to the inspectors to inspect the sales premises.
Agenda Item No.18 Consideration of the question as to what standards may be adopted in regard to metal particles found in eye ointments.	The Committee discussed the question and recommended that manufacturers of metal tubes in the country should be requested to follow the British Standards Institution specification for metal particles in eye ointment tubes. The Indian Standards Institution it was agreed, should also be requested to draw up similar standards for use in this country.	1. The manufacturers of metal tubes have been requested vide this Directorate letter No.53-9/68-D dated 16.10.69, copy endorsed to all State Drugs Control authorities that the metal tubes manufactured by them should conform to the British Standards Institution specification. A copy of the test for metal particles in collapsise tubes as given in British Standard Institution specification B S 4230-1967 was also sent to them. 2. The Indian Standards Institution which was requested by this Directorate to draw up the standards for *metal particles in eye ointments tubes*

(1)	(2)	(3)
		has agreed to the formulation of an Indian Standard for the item. Necessary action in the matter is being taken.
Agenda Item No.19		
Suggestion to change the packing of Absorbent Cotton Wool.	The Chairman explained to the Committee that recently the Defence Ministry had sent a communication stating that the manufacturers of surgical dressings were unable to attain the Indian Standards Institution specifications, even though the I.S.I. specifications were drawn up keeping in view the performance potentialities of the handloom sector. The points raised by the Defence Ministry, it was mentioned, had been forwarded to the I.S.I. for its comments.	The suggestion of DGAFMS have been considered by I.S.I. which agreed with the proposal of DGAF (MS) to modify the Indian Standards in view of the difficulties faced by the Ministry of Defence in obtaining supplies from the handloom industry conforming to the respective Indian Standards.
	The Committee recommended that if polythene packing for absorbent cotton wool was found to maintain the sterility of the packs it could be suggested for adoption by manufacturers for packing 4 oz. and bigger packs of Absorbent Cotton Wool. It was decided that the Director, Central Indian Pharmacopoeia Laboratory, Ghaziabad should be requested to carry out study on the suitability of polythene packs and give his opinion. The Drugs Laboratory, Baroda may also be requested to collaborate with the Central Indian Pharmacopoeia Laboratory in this study.	The Director, Central Indian Pharmacopoeia Laboratory, Ghaziabad has been requested to carry out the study on the suitability of polythene packing for absorbent cotton in collaboration with the Drugs Laboratory, Baroda. The report of his findings is awaited.
	Pending report on the suitability of polythene packs manufacturers should be asked to comply with the present labelling provisions for absorbent cotton wool. It was further decided that manufacturers should be advised to maintain conditions that which would prevent contamination during manufacture. Those manufacturers who sterilize Absorbent Cotton Wool should be asked to continue displaying the labelling legend "sterilized when	The decision of the Drugs Consultative Committee was conveyed to the State Drugs Control authorities vide this Dte. letter No.53-44/68-D dated 24.2.1969 requesting them to issue necessary instructions to the manufacturers of Absorbent Cotton Wool in their respective state to comply with

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	made to be sterilized before use". Other manufacturers may display the legend, "To be sterilized before use". The Committee agreed that no action should be taken against manufacturers of absorbent cotton wool on the basis of an analytical report declaring the product to have failed to pass the sterility test.	the labelling requirements as recommended by the Committee.
Agenda Item No.20		
Manufacture of aspirin tablets I.P. in chewable form for children.	The Committee considered the points raised by the Director, Drug Control Administration, Gujarat and also examined the packing of 'Me-Joral' and 'Minalgets' containing Aspirin, which are now being marketed. The Committee recommended that aspirin tablets in chewable form for children should be permitted to be marketed in dosage 75mg. of aspirin per tablet and each packing should contain not more than 10 tablets. No special legend was considered necessary.	The decision of the Drugs Consultative Committee was conveyed to the State Drugs Control authorities vide this Directorate letter No.53-45/68-D dated 13.2.1969 for implemention.
Agenda Item No.24		
Arrangements to be made for testing of finished Homoeopathic medicines.	The Chairman explained that while mother tinctures could be subjected to assay, no methods of testing of Homeopathic potency preparations have been developed so far and that in the absence of methods of test, it would not be posible to test Homoeopathic potency preparations. He however, said that M/s. Bhandari & Sons who are one of the leading manufacturers of Homoeopathic drugs would be asked to obtain any information on the subject which their principles in Germany may have with them.	Two leading German firms (1) M/s. Dr. Madaus & Co. (2) M/s Dr.Willmor Schwabe who are the manufacturers of Homeopathic drugs were approached by M/s. Bandari & Sons to furnish the information regarding the procedure developed lately in Germany for testing Homeopathic preparation for their potency. They have informed that no reliable method has so far been developed beyond testing the provings upto 7x, 8x resulting from observations of paper Chromatogrammes and Capillary strips under X-ray. This information was commu-

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		nicated to Drugs Control authorities of the State vide this Directorate letter No.53-49/68-D, dated the 11.8.1969.
Agenda Item No.25 Provision may be made to levy penalty in the case of loan licensees who fail to apply for renewal of licences before expiry.	The Chairman stated that certain provisions were now being made in the rules and forms for loan licences. The suggestions made for the introduction of a provision for levy of penalty in the case of loan licensees who failed to apply for renewal of loan licences before expiry would be taken into account while processing the amendments.	Necessary provisions to the effect is being made in the rules and forms for loan licences.
Agenda Item No.25 Consideration of the question of laying down provision in the rules for licensing of approved testing laboratories.	It was recommended that the testing laboratories should be licensed under the Drugs and Cosmetics Rules and that the terms and conditions under such licences should be examined, by a Sub-Committee consisting of the following members : 1. Shri. M.K. Rangnekar, Director, Drugs Control Admn., Maharashtra ... Member 2. Dr. B.B. Sarker, Director, Drugs Control, West Bengal. ... Member 3. Dr. R.L. Chopra, Drugs Controller, Haryana ... Member 4. Shri R. Balasubramanyam, Deputy Drugs Controller(India) West Zone ... Convener The Sub-Committee will also recommend the amendments in the Drugs and Cosmetics Rules that will have to be made in this connection.	The matter has been referred to the Sub-Committee of the Drugs Consultative Committee for examination.

(1)	(2)	(3)
Agenda Item No.28		
(1) Consideration of the difficulties faced by the Drug Control Administration in exercising control over cosmetics. (i) Facilities for testing of raw materials.	A. It was recommended that the manufacturers of Cosmetics in the country might be advised to adopt the I.S.I. standards, wherever these have been laid down for raw materials to be used in cosmetics. B. The Committee further recommended that wherever standards for raw materials for cosmetics had not been laid down by the I.S.I. specifications for such raw materials as laid down by the Toilet Goods Association of U.S.A. (T.G.A. Standards) and by the Toilet Preparations Federation of the U.K. (T.P.F. Standards) might be suggested for adoption by manufacturers.	A list of Indian Standards published by the I.S.I. covering raw materials used in the manufacture of cosmetics and toilet goods was circulated to all the State Drugs Control authorities under this Directorate letter No.53-51/68-D dt.28.4.69 for information and guidance.
(iv) Minimum conditions for manufacture of nail lacquars.	Shri Rangnekar explained the hazards that may arise in the manufacture of nail lacquers and informed the Committee that the Drug Control Administration, Maharashtra had drawn up a note giving the safety measures that should be adopted by manufacturers of nail lacquers. The committee recommended that this note might be circulated to the members for information and guidance.	A copy of note prepared by the Director, Drugs control Administration, Maharashtra stipulating the safety measures that should be adopted by manufacturers of nail lacquers was circulated to the State Drugs Control authorities vide this Dte. letter No.53-51/68-D dt.18.7.1969 for information and guidance.
Agenda Item No.29		
Consideration of the question whether ADRENALINE INJECTION should be packed in amber coloured or colourless glass ampoules.	It was decided that adrenaline injection, for which a life period of twelve months has been laid down and which is required to be sold in single dose containers should be packed in colourless glass ampoules. The glass container should be packed in cartons.	The decision taken at the Drugs Consultative Committee was conveyed to its members vide this Dte. letter No.53-52/68-D dt.10.2.69 requesting them to inform the manufacturers in their respective states to comply with this decision.

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Agenda Item No.30		
Consideration of the principles to be followed for institution of prosecutions under the Drugs and Cosmetics Act.	The Committee, after detailed discussions, reiterated the stand taken by it at its eleventh meeting. It also felt that its view-point had been sufficiently spelt out in the "Instruction Manual" supplied to the Drugs Inspectors at the time when the training programme for Drugs Inspectors was held in Maharashtra and Gujarat in 1962. The Committee further recommended that its views expressed at the Calcutta meetings supplemented by the advice given in the Instruction Manual could be followed as a guide line by the State Drug Control Administrations in deciding upon the action to be taken against offences under the Drugs and Cosmetics Act.	The guidelines that should be adopted by the State Drugs Control authorities for Institution of Prosecution under Drugs and Cosmetics Act and Rules thereunder were communicated to them vide this Dte. letter No.53-53/69-D dt.5.2.1969 for compliance.
Agenda Item No.32		
Suggestion that further conditions should be incorporated in Rules 74 and 78 to ensure good manufacturing practices and processing of drugs.	The Committee accepted the suggestion in principle. Since the suggestion required detailed examination the Committee recommended that the Sub-Committee Constituted under item 26 of the Agenda might also consider the proposal.	The matter has been referred to the Sub-Committee of the Drugs Consultative Committee for examination.
Agenda Item No.33		
Suggestions that the additional provisions should be included in Schedule 'M'.	The Committee agreed that the suggestion for including additional provisions in Schedule 'M' might be considered by the Sub-Committee appointed under item 21 of the Agenda.	The matter has been referred to the Sub-Committee of the Drugs Consultative Committee for examination.
Agenda Item No.34		
Any other item with the approval of the Chair.		

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1. Fees for duplicate copy of the renewal certificate in Form 21-C, and Loan Licences etc.	The Chairman stated that an overall check will be made of the provisions relating to grant or renewal licences and for grant of duplicate copies of licences and necessary action taken to set right any deficiencies.	Necessary provisions are being made in the Drugs and Cosmetics Rules.
2. Maintenance of Inspection Book for licence holders in Form 25 (B) :-	It was explained that a new form setting forth the manner in which an Inspection Book is to be maintained by the licensees was now under publication in final form.	The Form in which the Inspection book is to be maintained has been published in the final form.
4. Duties of Government analyst to test samples of cosmetics.	The Committee recommended that rule 45 of the Drugs and Cosmetics Rules may be amended to add the words "and cosmetics" after the words 'drug'.	The proposal has been referred to by the Ministry of Health & F.P. to the Drugs Technical Advisory Board for its consideration.
5. Labelling requirements for cosmetics showing of the manufacturing licence number.	The Chairman stated that the proposal was considered at the Drugs Conference held in Calcutta in 1967 and the opinion that prevailed was that the manufacturing licence number need not be shown on the label of cosmetics. The members of the Committee felt that the statutory requirements that dealers should buy cosmetics from a licensed manufacturers cannot be fulfilled unless the manufacturing licence is shown on the label. This aspect, the Committee felt, should be brought to the notice of Government.	The views of the Drugs Consultative Committee has been brought to the notice of the Govt. of India, Ministry of Health & F.P., U.D. The decision of the Government is awaited.
6. Clarification regarding entry 1 to Schedule 'K' of the Drugs and Cosmetics Rules in respect of items like Petroleum Jelly, soda bicarb, Glycerine etc. which are labelled as "Not	The question had also been discussed at the Drugs Conference held on the 16th & 17th September, 1968 at Cochin. The Committee agreed that the list of items which the manufacturers' organisation promised to supply should be examined and that meanwhile items like Glycerine, Dextrose, Boric Acid, Kaolin, Soda-Bicarb, Talc, Liquid Glucose, and such other items as may come to the notice of the State Drug Control authorities may be permitted to be used by the manufacturers of drugs after being	The list of raw materials used by the manufacturers of drugs and which are often not marketed with a pharmacopoeial suffix e.g. I.P., B.P., U.S.P etc. has been obained from the various manufacturers association and the list is under examination of this Directorate.

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for medicinal use".	tested and found to be of quality even though they are labelled 'Not for medicinal use'.	
9. Consideration of the question of laying down standards for raw materials to be used in the manufacture of Petroleum Jelly of Pharmacopoeial quality.	The Committee recommended that strict control should be exercised over the manufacture of Petroleum Jelly and the quality of raw materials like microcrystalline wax and pale oil used for manufacture of petroleum jelly. The specifications of Petroleum Jelly compiled by the Director, Drugs Control Administration, Maharashtra, it was agreed, should be adopted by the Drug Control authorities of the States. In regard to the suggestion made for deleting the standards for yellow Petroleum Jelly (Yellow Soft Paraffin) in the Indian Pharmacopoeia 1966, the Chairman stated that this item is used in large quantity by the manufacturers. It will be necessary to make an enquiry from the manufacturers who use yellow petroleum jelly as to whether the monograph for this drug should be retained or deleted from the I.P.1966. The suggestions received from manufacturers would be passed on to the Indian Pharmacopoeia Committee for necessary action.	A copy of the specifications in respect of raw material required for the manufacture of Petroleum jelly as compiled by the Director, Drugs Control Administration , Maharashtra was circulated to the Drugs Control authoritiesof the States vide this Dte. Letter No.53-32/68-D dated the 13.2.1969. Certain State Drugs Control authorities after ascertaining the views of the manufacturers in their respective States have forwarded their suggestions whether the monograph of yellow Petroleum jelly should be retained or deleted from the I.P. 1966. The suggestions have been passed on to the Indian Pharmacopoeia Committee for necessary action.
10. Consideration of the question of laying down minimum conditions for manufacture of Ophthalmic Ointment.	The Committee after discussion agreed that the recommendations made by the Drugs Control Administration, Maharashtra under which the manufacture of Opthalmic Ointments should be carried out might be adopted by other States.	The minimum conditions for manufacture of Opthalmic Ointments as drawn up by the Director, Drug Control Administration, Maharashtra were communicated to all the State Drugs Control authorities vide this Directorate Letter No.53-30/68-D dated the 22.2.1969 for their information and guidance The Director, Drugs Control, West Bengal was of the view that the conditions under which the manufacture of Ophthalmic Ointments should

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		be carried out as drawn up by the Director, Drugs Control Administration, Maharashtra should have a statutory backing list they were challenged in a Court of law. The question whether these requirements for manufacture of Ophthalmic Ointments prepared by the Director, Drugs Control Administration, Maharasthra should be incorporated in the Drug Rules would be discussed at the next meeting of the Drugs Consultative Committee.
11. Consideration of the question of laying down upper limits for Antibiotic formulations.	The Committee recommended that no overages of antibiotic in formulations should be permitted except to the extent prescribed in the individual monograph of the Pharmacopoeias. For anti-fungal antibiotics, however, the Food and Drug Administration of the U.S.A. had laid down certain limits for overages which could be adopted.	The limits for overages in respect of antifungal antibiotics in formulations as specified by the Food and Drug Administration of U.S.A. were communicated to Drugs Control authorities of States vide this Dte. Letter No.53-71/68-D dated the 21.8.1969 for information and guidance.
12. Consideration of the question of laying down sampling by repackers of repacked drugs.	The Committee considered the scale of sampling of repacked drugs in the light of the scale of sampling that has been adopted by the Drugs Control Administration, Maharashtra. It was agreed that if the drug to be repacked is purchased in 5 containers and if all the containers bear the same batch number then samples from two containers should be drawn and without mixing them the same should be sent for test and analysis. If reports on both the samples are found to be of standard quality the drug contained in the 5 containers bearing the same batch number should be deemed to be of standard quality and permitted to be repacked. In case the purchase is from 5 to 10 containers of the same batch, 4 samples should be drawn and sent for test and analysis and the drug reported to be standard quality, if all the samples pass	The decision taken at the Drugs Consultative Committee was conveyed to the Drug Control authorities of the States vide this Directorate Letter No.53-63/68-D dated 29.4.1969 for implementation.

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	the tests. In case the purchase is from 10 to 15 containers, 5 samples should be sent and the drug would be reported of standard quality if all the 5 samples pass the tests. If the purchase is from 15 to 20 containers, six samples should be sent for test and analysis and if are reported to be of standard quality the same should be permitted to be used. In case the containers bear different batch numbers the same procedure shall be followed in case of containers with the same batch number.	
14. Action to be taken in respect of Rubber Contraceptives reported to be "Not of standard quality".	The Chairman stated that the question of testing condoms which are imported with or manufactured in the country had been discussed with the manufacturers and that the decision taken had been communicated to the State Drug Control authorities. The Family Planning Department was keen on ensuring that only condoms of standard quality are permitted to be marketed. It was therefore necessary to exercise strict control over condoms which are imported and manufactured and that no relaxation from the existing provisions should be permitted. The scale of sampling of cendoms from the premises of dealers or manufacturers is yet to be decided on a statistical basis and Chairman requested Shri Patel and Rangnekar to expedite their discussions with the statistical authorities.	The scale of sampling of cendoms that may be adopted for testing from the premises of dealers or manufacturers will be discussed again at the forthcoming meeting of the Drugs Consultative Committee.
15. Consideration of the question of colouring of coated tablets.	The Committee decided that no colour need be permitted to be added to Pharmacopoeial preparations unless the use of a colour was specifically permitted in their case in the respective pharmacopoeia.	Action on this decision has to be taken by the State Drugs Control Organisation. Rule 127 of the Drugs and Cosmetics Rules is now being amended to include colours which are to be permitted to be used in Patent or Proprietory medicines in persuance of the provision contained in the Sections 9B and 17B of the Drugs and Cosmetics Act. The amendment to this rule when finally published

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		will be forwarded to the State Drugs Control authorities for information necessary action.
16. Consideration of difficulties experienced by the Government Analyst in reporting on Form No.34 of the Drugs and Cosmetics Rules.	The Committee considered the difficulties experienced by Government Analysts in issuing reports on cosmetics in Form 34 which was inadequate for the purpose. It was agreed that the Director, Drugs Control Administration, Maharashtra and Gujarat should consult their Government Analysts and Suggest the specific changes that should be made in the form.	The Director, Drugs Control Administration, Gujarat and Maharashtra were requested to consult their Government Analysts and suggest the specific changes that should be made in Form 34. The D.C.A., Gujarat has in farmed that his Government Analysts feel that the Form 34 should be modified in such a way that the Government Analyst finds no difficulty in reporting on the cosmetic samples. This he said could be done by a discussion at the meeting of the Govt. Analysts only. The D.C.A., Gujarat had also endorsed the views of his Govt. Analysts. The reply, however from Govt. Analyst Maharashtra is awaited.
26. Provision for realisation of fees for duplicate copy of certificate of renewal of licences.	The Committee recommended that necessary provision for issue of duplicate copies of certificates of renewal of licences and fees therefore should be provided in all cases in the Drugs and Cosmetics Rules.	Necessary provisions are being made in the Drugs and Cosmetics Rules.
27. Licence forms may be amended so that Licensee cannot sell drugs from the premises in any other name and style than mentioned in the licence.	The Drugs Controller, Kerala stated that his suggestion was a sequal to a judgement of the Kerala High Court. The Chairman desired that a copy of the judgement might be sent to him so that the proposal could be examined further.	The Judgement of the Kerala High Court forwarded by the Drugs Control authority, Kerala State was examined by this Dte. It was felt that there was no need for amending the licence forms so that the licensee cannot sell drugs from the premises in any other

(1)	(2)	(3)
		name and style than mentioned in the licence as the Drugs Rules contain provision for preventing such activities.
28. Suggestion to amend the rules to levy pro-rata fees for renewal of licence after the expiry of licence.	The Chairman explained to the Committee that the Committee's recommendations for the levy of a pro-rata fee for renewal of a licence after its expiry was supported by the Drugs Technical Advisory Board. The Govt. of India, however, did not accept the recommendation.	The Drugs Technical Advisory Board at its meeting held on the 13th Nov. 1968 had considered the proposal for levy of penalty on pro-rata basis for default in submitting the application for renewal within grace period. The Board agreed to the proposal and necessary provision for levy of penalty on a pro-rata basis of the licence fee for default in submission of an application for renewal of licence after the expiry of the grace period, is being made in the Drugs and Cosmetics Rules.
29. Relabelling (Redressing) of Drugs and Cosmetics.	Kerala Drugs Controller desired to know whether the practice followed by certain firms to send labelled stocks to their own storage depots in different states and to send separately the labels for being affixed on them should be permitted. The Committee was of the view that no stocks of drugs should be allowed to go out of manufacturing premises without being labelled properly and if any firm was found not to conform to this requirement, particulars of the firm should be furnished by the Drug Control Authority of the State in which such cases were detected to the authorities of the State where the manufacturing firm is located.	The decision of the Drugs Consultative Committee was conveyed to the State Drugs Control authorities under this Directorate Letter No.53-77/68-D dated 31.3.1969 for implementation.
32. Permision for availingof testing facilities of drug testing laboratories by manufacturers who do not have their own facility of testing.	The Committee recommended that the Sub-Committee appointed under item 26 should consider this aspect also.	The matter has been referred to the Sub-Committee of the Drugs Consultative Committee for examination.

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33. Filling of gelatin capsules by hand.	The Committee recommended that the filling of capsules should be done with at least semi-automatic filling machines.	The decision taken at the meeting of the Drugs Consultative Committee was conveyed to the Drugs Control authorities of the States under this Dte. Letter No.53-4/68-D dated 10.3.1969 for implementation.
39. Consideration of the interpretation of the term 'New Drug' was defined in the Drugs and Cosmetics Rules, 1945.	The Committee discussed the item and agreed that a 'New Drug' eventhough approved for a particular firm would continue to be a new drug for other parties also until it is absorbed in a prescribed pharmacopoeia. It is necessary that all firm which want to import or manufacture such 'New drug' should be made to obtain the approval from the Central Drugs Control Administration as Standards in many cases for these New Drugs vary	The decision taken at the Drugs Consultative Committee was communicated to the State Drugs Control authorities vide this Dte. Letter No.53-81/68-D, dated the 31.3.1969 for compliance.
(i) Standard for Clinical Thermometers.	The Committee agreed that the manufacturers should be persuaded to take out I.S.I. certification Licence. It was further recommended that a note on the facilities provided by the I.S.I. for testing of clinical thermometers under the I.S.I. Scheme and also the list of manufacturers of clinical thermometers in the country as supplied by the I.S.I. should be circulated to the members.	A note on the facilities provided by the I.S.I. for the testing of Clinical thermometers under the I.S.I. Scheme and also the list of manufacturers of Clinical thermometer in the country as supplied by the I.S.I. were circulated to the State Drugs Control authorities under this Dte. Letter No. 53-11/68-D dated 18.12.1968.
(ii) Ban on Pencillin Ointment.	The Committee observed that there was no specific provisions to ban the marketing of such items. It was recommended that an omnibus provision should be introduced in the Drugs and Cosmetics Act enabling Govt. to prevent the marketing of drugs which constitute a positive health hazard to human beings.	The recommendation of the Committee will be kept in mind when the Act is amended next.

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(iii) Amendment of Form 21.	Shri. Patel pointed out that in licence Form 21, the words "and to operate a pharmacy on the premises situated at subject to the condition specified below and to the provision of the Drugs and Cosmetics Act, 1940 and the rules there under" are not laid down though the form 20 provides for the operation of a pharmacy. The Committee agreed that suitable change should be made in Form 21.	The proposal to amend form 21, has been referred by the Ministry of Health and family planning to the Drugs Technical Advisory Board for its consideration.

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ANNEXURE - II
Item No.53 of
13th D.C.C.
Meeting

Requirements for manufacturing Cosmetics

(See Rule 139)

1. Location and surrounding - The factory shall be located in sanitary place and all the hygienic conditions should be maintained in the premises. Premises should not be used for residence or interconnected with residential place. These should be well ventilated and clean. Lunch Room should be provided in larger units. Rest room for workers and canteen arrangements may be provided wherever required.

2. Water supply - The water used in the manufacture shall be pure and of drinkable quality.

3. Disposal of waste water - Suitable arrangements should be made to dispose of waste water.

4. Health clothing and sanitary requirement - Workers should be free from contagious or abnoxious diseases. They should be provided with clean uniforms, masks, head gears whenever required Hand gloves in powder sections should be provided for workers. Washing facilities for workers should be provided.

5. Medical services - Adequate facilities for first aid should be provided.

6. Packing Section - Working benches shall be provided for carrying out filling, labelling, packing etc. and such tables should be covered with impervious washable tops.

Requirements of Plant & Equipments

(A) Powders - Face, Talcum, Baby Powders - An area of 100 Square feet is recommended for basic installations.

Area should be kept dust free by providing a suitable number of exhaust fans.

1. Sieves of adequate meshsize.

2. Mixer - of adequate size either of stainless stell or aluminium.

3. Suitable filling equipment.

4. Storage containers for stocking finished products.

5. Stainless steel scoops and spoons.

(B) Creams - Creams Facial, Lotions, Brilliantines, Depilatory Creams, Hair Oils etc. Eye Liner, lipsticks.

1. Mixing and storage vessels - Either of stainless steel, tinned copper or brass, or aluminium.

2. Suitable power driven or handdriven, verticle stirrer

3. Tripple Roller mill and Electric Kettles for lipsticks.

4. Suitable gravity fillers.
An area of 14 square meters is recommended for basic installations.
Use of distilled water is recommended in Creams.

(C) Kajal

1. Premises - (a) Minimum areas should be 9.5 square meters, exclusively for this product.
   (b) Walls should be plastered smooth and with light washable paint.
   (c) Flooring should be smooth.
   (d) False ceiling should be provided wherever required.
   (e) Manufacturing area should be made fly proof by providing with an air lock.

2. Procees -

   (i) Base used for Kajal should be heat sterilised by heating the base at 150° C for 1 1/2 hour.

(ii) The vegetable carbon Black Powder should be heated in drying oven for 120°C for 1 hour.

(iii) The ingredients then should be mixed well and added with items like Camphor in cold condition as the case may be

All the utensils used for manufacture should be of stainless stell and should be washed with detergens, Water Antiseptic liquid and again with pure water.

Containers used for 'Kajal' either plastic or tin, should be sterilised by immersing in boiling water if possible and also be cleaned thoroughly and also with antiseptic solution.

(iv) Spatulas, spoons etc. used should be of stainless steel and treated with antiseptic liquids as above.

(v) The workers should put on clean overalls and use hand gloves wherever necessary.

An area of 9.5 square meters is recommended for basic installations and packing of Kajal.

(D) Nail Polish -

1. Storage and mixing vessels stainless steel mildsteel or glass.

2. Gravity filling arrangement.

An area of 9.5 square meters for basic installations including storage of raw material and packing is recommended.

Manufacture of Nail Polish should not be allowed in residential localities and they should as far as possible be permitted in Industrial area - Also No Objection Certificate from local fire bragade authorities should be insisted for.

Minimum safety measures to be adopted by manufacturers engaged in manufacture of Nail Lacquars.

Manufacture of Nail Lacquars involves hazardous operations and requires all the possible safety precautions to be adopted to prevent accidential fire and explosion hazards. Following precautions are suggested in manufacture of Nail Lacquers.

1. **Premises**

i) As far as possible premises should be situated in Industrial Estates.

ii) They should be separated from other cosmetic manufacturing area by metal partitions of at least 2.4 square meters height.

iii) They should be sufficiently airy and sufficient number of exhaust fans should be provided.

iv) Oxychloride flooring should be provided or the flooring should be coated with oxychloride paint or fire proof paint or floor should be covered with fire proof sheets.

v) The flooring level of the section should be six inches below the general flooring level.

vi) Smoking, cooking or dwelling should not be permitted and no naked flame should be brought in the premises.

vii) No wooden loft should be permitted and if wooden loft already exists, it should be covered with metal sheet.

viii) All electrical wiring and connection should be made through conduit pipes Main electrical control should be kept outside the manufacturing area.

ix) All the equipment, Motors electrical lighting should be flame proof.

x) Fire extinguishers like foam and dry powder and sufficient number of buckets containing sand and clean water should be provided.

2. **Storage**

All the explosive solvents and ingredients should be stored in metal cupboards.

3. **Manufacture**

i) The manufacture of lacquers should not be undertaken if (viii) and (ix) cannot be complied with. This should be obtained ready made from item No.1 lacquar manufacturers.

ii) Workers should be asked to wear shoes with rubber sole.

4. Besides above guidelines manufacturers must obtain, no objection certificates from local municipal authorities and should comply with their requirements also.

Tooth Powder

Manufacture of tooth powders having precipitated chalk base can be permitted in face powder section provided adequate precautions are taken for cleaning the equipment thoroughly to avoid mix up and contamination. Manufacture of Black Tooth Powder should be separate and an area of 9.5 square meters is recommended for basic installations. Following equipment is recommended -

1. Ball Mill type mixer of adequate size either of Mildsteel, stainless steel or Aluminium of thicker guage.

2. Suitable sifting devise.

3. Mixing and storage stainless steel containers for preparation of flavouring solution having medicinal properties.

4. Suitable filling devise.

(F) **Aerosol Products**

1. Mixing and storage tanks for preparation of concentrate.

2. Purging, concentrate filling, and propellant filling, automatic devise.

3. Leakage testing apparatus.
An area of 9.5 square meters is recommended for basic installations.

(G) **Liquid Products** - Toilet waters, Alcoholic fragnance solutions, shampoos etc.

1. Storage and mixing stainless steel vessels.

2. Suitable filteration arrangement.

3. Suitable filling arrangement.

Minimum area of 9.5 square meters is recommended for basic installations. Requirements of alcohol excise banks also may be taken into consideration. Besides above arrangements for packing of the products area recommended 9.5 square meters, storage of raw materials, packing materials and finished products area recommended 15 square meteris should be provided separately. Also arrangements for washing containers and drying of the bottles. Mechanical drier should be provided.

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Suggested minimum specifications for certain categories of finished cosmetics products -

Powders : Talcum, Face, Borated, etc.

1.	Appearance	should compare with manufacturer's own standard sample.
2.	Colour	
3.	Perfume	
4.	Feel	
5.	Fineness	Powder should not be 0 less than 200 mesh size.
6.	pH	Between 6 to 10
7.	Colours	should contain colours. Included in Schedule Q to Drugs & Cosmetics Rules 1945 as amended.
8.	Active Ingredients	Active Ingredients like Boric Acid, Hexachlorophene, should be present within the permissible limits fixed by the manufacturer.

Creams Vanishing creams, cold creams, bleaching whitening etc. facial creams.

1.	Stability	should compare with manufacturer's own standard samples.
2.	Appearance	
3.	Colour	
4.	Odour	
5.	Consistency	
6.	pH	Between 6 to 8
		Creams should be subjected to extreme high and low temperatures to study the stability of creams before marketing.
7.	Active Ingredients	Active Ingredients like Ammoniated mercury andother mercurial salts should be estimated in the creams, wherever applicable.

Hair Oils

1.	Appearance	should compare with manufacturer's own standard sample.

2.	Colour	should compare with manufacturer's own standard sample.
3.	Odour	
4.	Viscovity	
5.	Acid value	Not more than 6 in Hair Oils with coconut Oil and not more than 2 in case of Hair Oils Manufactured with other vegetable oils. Should not contain colours other than those which are included in Schedule 'Q' to Drugs and Cosmetics Rules 1945, as amended.

Depilatory Creams Powders

Contents of active ingredients such as metallic sulphides or thioglycollates etc should be estimated quantitatively and should be present within permissible limits fixed by the manufacturers.

Hair Dyes

Content of active ingredients like paraphenylene diamine, metallic sulphides etc. should be estimated quantitatively and should be present within permissible limits fixed by the manufacturers.

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