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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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MINUTES OF THE SEVENTEENTH MEETING OF THE DRUGS CONSULTATIVE COMMITTEE HELD AT NEW DELHI ON THE 24TH AND 25TH JANUARY, 1974

The Chairman welcomed the members of the committee and in his address set out a number of important subjects which needed prompt attention and determined action on the part of the Central and State Drug Control authorities. The salient points of his address are summarised below :-

1. Shortages of raw materials, chemicals, solvents, fuel oil for boilers etc have been reported in the international market. This situation will have its repercussions on the drug industry in the country. Growing shortage of raw materials might force manufacturers to cut on production which, inturn, would tempt dealers to drive stocks of drugs underground and sell them at exorbitant prices. It is therefore necessary for Drug Control Authorities to exercise a close watch to ensure that drugs are sold at the prices indicated on their labels. The need for maintaining the supply position of drugs, paritcularly the commonly-used household remedies, has been emphasised by the Prime Minister. A two-pronged action would therefore be called for. First, the quantitative production of basic drugs by manufacturers may have to be watched and secondly, the distribution of such drugs may also have to be kept under surveillance. Such an action may help in preventing black marketing of bulk drugs and raw materials. Similarly the movement of house hold remedies and life saving drugs could be watched. The Zonal Officers will assist the State Drug Control authorities with the list of bulk drug manufacturers in their

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

ITEM NO.29

Possession of Psychotropic drugs by individuals.

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

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

ITEM NO.30

Sale of drugs by hospitals to patients at exorbitant prices.

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

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

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

Zones, to help a watch being kept on the movement of bulk drugs and essential drug formulations.

2. Shortages in supplies give scope for drug fakers to cash in on the situation. There is evidence that the incidence of spurious drugs is vide-spread in the country. This poses a grave threat to public health. The following steps were recommended to tackle spurious drugs :-

(a) The Drug Control Organisations should make arrangements, through the State Governments, for requisitioning police help at Short notice and facilities for quick transport of police and drug control personnel for carrying out raids.

(b) State Drug Control Organisations should also be enabled to obtain the services of experienced counsels for fighting cases relating to spurious drugs.

(c) Dealers whose bonafides are suspect should be kept under surveillance. Where purchases and sales without cash memo are resorted to and the dealers are not able to account for the stocks of drugs held by them, cancellation or suspension of their sale licences or even prosecutions should be undertaken. Frequent inspections of stocks of drugs with dealers will have a salutary effect on the movement of spurious drugs.

(d) The Co-operation of the drug industry should be sought in tackling, spurious drugs and firms whose products are duplicated should be advised to keep a watch on the movement of such drugs through their medical representatives and pass on useful clues about the possible source and retail outlets to the officers of the Drug Control Organisations.

(e) Drugs Inspectors at the district level should keep in touch with dealers, inform them of the movement of

spurious drugs and warn them of stern action against dealers who are found selling or stocking spurious drugs. Such warnings might help in creating the right climate for improving the ethics of the drug trade.

(f) Public support should be fully mobilised in the campaign against spurious drugs. Consumer Groups, the medical profession & social workers should be particularly contacted. The public should be educated to buy drugs from licensed dealers and to insist on Cash memos. Shops selling drugs at suspiciously low prices should be brought to the notice of Drugs Control authorities. Dates of expiry of potency of drugs must be checked by Consumers before accepting them. All used containers of drugs should be destroyed. The public should be educated through advertisements in Cinema houses and local language newspapers.

(g) Doctors should make sure that they buy drugs only from authorised dealers, and not from unauthorised sources. Any unusual changes noticed by them in the appearance or efficacy of the drugs should be reported to the State Drug Control authorities.

(h) The common belief among the people is that since hospitals buy drug from the cheapest source, quality drugs are not available from hospitals. Medical Stores in hospitals need to be checked frequently by Inspectors also, the storage conditions maintained for drug, manner in which they are purchased & used and the steps which hospitals take to prevent the misuse of narcotic and psychotropic drugs should be closely watched.

(i) Firms which execute orders for drugs for Government and other institutions should be subjected to frequent inspections to make sure that they observe "Good

Manufacturing Practices" and take adequate precautions to maintain the stability and efficacy of formulations manufactured by them.

3. Two important Organisations namely, the Consumer Council of India and the Citizens Council are seriously seized of the problem of drug administration in the country and are touring the States and giving publicity to the deficiencies observed. It would be useful to keep the points, set out above, in mind and implement them.

4. The provisions of the Drugs & Cosmetics Act relating to Ayurvedic Drugs & Cosmetics, particularly the licensing of manufacturing firms have not been implemented in many States. States which are remiss in this direction should licence all Ayurvedic and Unani manufacturers and then proceed to screen the list of drugs manufactured by them.

A close watch should be kept over commonly used cosmetics such as hair dyes, lipsticks, eye-brow pencils, shaving lotions etc. Surma & Kajal manufacturers also need to be watched for the type of raw materials used by them some of which are reported to be toxic.

5. The West Bengal Government have brought forward a Drug Amendment Bill which **inter alia** provides for life imprisonment for all drug offences. The decision of the Central Government regarding the changes proposed in the Bill is awaited. Whatever changes are accepted in the West Bengal State Drug Control Legislation, will have to be made in the Central Legislation. This opportunity should be availed of for introducing in the Act important changes that are necessary. (A note on the changes that would be necessary in the Act was circulated) It was decided that a sub-committee consisting of Shri Shanbhogue and Shri Rangnekar should process the suggestions taking into consideration the changes proposed in the note and the views of other members of the Committee and send the final list of amendments to the Chairman. It was agreed that Dr. Prem K. Gupta, A.D.C.(I) South Zone, Shri Rajadhaksha and Shri Kattishettar would assist the sub-committee in

the finalisation of these proposals.

6. Regular training programmes are being Organised by the Centre for Drugs Inspectors in Bombay and States should take advantage of this programme in getting their inspectors trained by deputing them in time for the course.

7. Proposals were made to the Planning Commission for setting up combined Food & Drug Laboratories in States at a cost of Rs.40 Lakh for each laboratory during the Fifth Plan as a Centrally sponsored Scheme. Although the Plan resources do not appear encouraging, it is hoped that this Scheme would be accepted.

In regard to enforcement of the rules relating to Ayurvedic (including Siddha) and Unani drugs the chairman agreed to suggest to the Union Health Ministry that such of those States as have not taken a decision on the authority who should enforce the quality control measures over such drugs should be advised to expedite their decisions.

Speaking about the changes proposed in West Bengal Drug Amendment Act, the chairman stated that when the Central Government takes a decision, it would be circulated for the information of the members.

Shri Rajadhyaksha stated that over the years the basis for calculation of a units annual raw materiál requirements had been the best of past two years' consumption added by 15% extra to take care of growth. Recently the Ministry of Petroleum and Chemicals have issued a directive that the 15% provided for growth for the units registered with the DGTD, particularly the units in the organised sector may be discontinued and that only the best of past two years' consumption would be provided. He stated that representations had been received from such firms to the effect that such a reduction in the quantum of raw materials will come in the way of the growth and maximisation of production by the industry. He desired that all firms registered with the DGTD and which had been receiving raw materials on the basis of the past two years consumption plus 15 percent to cover growth should continue to be allowed the same quantum of raw materials.

Replying to this point, the chairman clarified that the Cabinet had, for sometime past, been concerned with certain firms, particularly foreign-subsidiary and monopoly firms exceeding the capacities licensed to them for manufacture of drugs. Individual Ministries were presumably advised by the Cabinet to take suitable steps against firms which have been producing drugs in excess of the licensed capacity. In the context of such a situation, the Chairman felt that no useful purpose will be served by the Drug Control Organisation taking up the issue with the Ministry of Petroleum & Chemicals.

With a view to screening sub-therapeutic formulations and new drugs by the State Drugs Control administrations in the country, the Chairman reterated the earlier decision taken by the Committee that a panel consisting of clinicians, pharmacologist and a Biochemist should be appointed in each State for this purpose.

At this stage, a special session was held mainly to discuss the enforcement of the provisions relating to Ayurvedic including (Siddha), Unani and Homoeopathic medicines, the difficulties that are encountered by the members, and ways and means of achieving uniformity of action in this regard. Dr. Jugal Kishore, Adviser in Homoeopathy and Hakim Razzack, Senior Research Officer, from the Ministry of Health participated in the discussions.

Dr. Jugal Kishore pointed out that Bihar and Uttar Pradesh lag behind in enforcing the rules relating to homoeopathic drugs in their respective States and should be requested to enforce the provisions without delay. He also desired that the recommendations of the sub-committee appointed by the Drugs Consultative Committee for laying down details of the equipments and staff to be employed for the manufacture of homoeopathic medicines should also be expedited. He also referred to certain Inter-State restrictions presently being imposed by Government on the movement of homoeopathic medicines and desired that such restrictions should be removed.

The Chairman assured the Committee that the points mentioned

by Dr. Jugal Kishore would be examined and the report of the sub-committee would be expedited. As regards restrictions on the movement of homoeopathic medicines, he advised Dr. Jugal Kishore to take up the matter with the Ministry of Finance.

Shri Shanbhogue desired to know whether homoeopathic injections can be recognised and certain homoepathic medicines named cholera tablets, malaria tablets etc. can be allowed to be marketed.

The Chairman clarified that recognition to homoeopathic injections has not been given under the Drugs & Cosmetics Act & Rules. He was also of the view that manufacturers of homoeopathic medicines should be discouraged from labelling their products in such a manner as to give the impression to consumers that they are cures for diseases e.g. cholera tablets, malaria pills etc.

Members sought Dr. Jugal Kishore's advice on the use of Homoeopathic Veterinary medicines. He said that homoeopathic drugs for veterinary use for common diseases could be made.

Shri Razzack stressed the need for appointing separate advisers for Ayurveda and Unani medicines in the State Drug Control administrations as required by the Drugs and Cosmetics Rules.

Shri Gulati of Delhi Administration referred to Form-24-D of Scheduled A and said that the prescribed application form refers to 'Grant/renewal of a licence to manufacture Ayurvedic (including Siddha) or Unani drugs' and enquired whether the licensing authority should issue one licence or two licences if the application was in respect of both Ayurvedic & Unani drugs. The Chairman was of the view that a combined licence could probably be issued.

Members stated that two circulars had been issued regarding the use of colouring agents in Ayurvedic preparations and desired to know what Procedure should be followed in allowing the use of colours. Chairman explained that the Ayurvedic Drugs Technical Advisory Board

which had examined the matter was of the view that the addition of any colours to Ayurvedic, Siddha or Unani Drugs would come in the way of easy identification, and that most of drugs of Indian System of Medicine might have a colour of their own, on the basis of the raw materials used. As such, the addition of colouring agents to such drugs should not be permitted. However, in the case of syrups and oils, the addition of permissible colouring agents has been agreed to by the Ayurvedic & Unani Drugs Technical Advisory Board.

On the question as to whether Ayurvedic injections should be allowed to be manufactured or not, the Chairman clarified that Ayurvedic injections should be treated as 'New drus' and that it should be ensured that such injections are sterile, apyrogenic and non-toxic before being allowed to be marketed. He agreed with members that Ayurvedic Drug Rules should be made to cover injectable preparations and requested Shri Razzack to take action in this regard.

Members desired to know whether loan licences for manufacturing Ayurvedic Siddha and Unani drugs could be permitted and whether the necessary rules were proposed to be introduced for the purpose.

The Chairman stated that this question had been considered by the Ayurvedic and Unani Drugs Technical Advisory Board and that it had agreed to the extension of the Scheme of loan manufacturing licences to Ayurvedic, Siddha or Unani drug manufacturers. Shri Razzack informed the Committee that suitable provisions in the rules are under consideration.

Chairman then thanked Dr. Jugal Kishore and Shri Razzack for having joined the discussions of the Committee.

The annual reviews of the activities of the State Drugs Control Organisations and those of the Zonal and Port Offices of the Central Drugs Standard Control Organisation were circulated for the information of the members.

The Committee then took up the agenda for consideration.

ITEM NO.1

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

The minutes were confirmed.

ITEM NOS.2 & 3

Action taken on the recommendations made by the Drugs Consultative Committee at its last meeting and the question arising out of the minutes.

Annexure - I

The Committee studied the note on the action taken and the questions arising out of the minutes of the last meeting together. The following observations were made :-

(i) **Misuse of Psychotropic substances.**

Members pointed out that M/s. Roussel were **not** supplying information regarding the supplies of 'Mandrax' made by them to hospitals and other institutions apart from trade channels and felt that this information should be insisted upon and the details is furnished. It was agreed that manufacturers of Psychotropic drugs should be advised to furnish the required information to the State Drugs Control Authorities.

(ii) The Chairman stated that detailed and exhaustive comments had been received on the recommendations contained in the report of the Sub-committee on the revision of the existing Schedules E,G,H and L and for exercising control over misuse of psychotropic substances, which had been circulated to the members earlier. He suggested

that Dr. Prem Kumar Gupta, Asstt. Drugs Controller (India), and Shri C.V. Narasimhan, Deputy Drugs Controller Tamil Nadu, should examined the comments received from the members and circulate to the members of the Committee the changes which in their opinion should be carried out in the Report. The Committee agreed to the suggestion.

(iii) **Storage conditions for antibiotic preparations**

The Chairman stated that under the Drugs & Cosmetics Rules, for drugs specified in Schedule P and their preparations, the life period was fixed under the conditions of storage notified by the licensing authority under sub-rule (i) of Rule 59. He recalled that notifications had been issued by the State Drug Control authorities specifying the conditions of storage for drugs including antibiotic preparations which required such preparations to be stored in a "Cool Place". Subsequent to this, the industry and the trade had represented that maintenance of "Cool Place" storage arrangement (i.e. between 8° - 15°C temp or alternatively storage under refrigerator) was difficult and that storage conditions applicable to antibiotics should be reviewed. Manufacturers do not normally recommend any special storage conditions for these preparations. To make sure that antibiotics keep well when stored in room temperature in the country, it was earlier decided to carry out a study on the stability of antibiotic preparations stored at room temperature in different parts of the Country. A plan for sampling antibiotics preparations was circulated to the members in which antibiotics preparations of Tetracycline and Penicillin including eye Ointment, injections, pediatric suspension, Capsules and tablets etc were chosen for sampling. Preparations having only six months

or less of the life period left were collected from State capitals and got tested at the three laboratories i.e. Drugs Laboratory, Gujarat, Drugs Control Laboratory, Maharashtra State and the Central Indian Pharmacopoeia Laboratory, Ghaziabad through the Zonal Officers. As the aim of the study was only to assess the stability of antibiotic preparations moving under different climatic conditions prevailing in the country, only an assessment of the potency of the preparations was carried out.

Under the first phase of study of the 77 samples drawn and tested upto 31st October, 1972 76 samples were found to be of standard quality and one sample **not** of standard quality.

In the Second phase of the sampling programme 124 samples of antibiotics were drawn and tested upto 10th December, 1973 for potency. 115 samples were found to be of standard quality and the remaining 9 samples **not** of standard quality for loss of potency.

In the light of the above study, the consensus view of the committee was that antibiotic preparations, by far and large, keep well on storage at room temperature under different climatic conditions obtaining in the country and that the licensing authorities should **not** insist on antibiotic preparations being stored in the refrigerator. It was futher agreed that for antibiotic preparations specified in Schedule P to the Drugs & Cosmetics Rules, the conditions of storage already notified by the Licensing Authorities should be revised accordingly.

(iv) **Use of Second hand bottles for filling transfusion solutions.**

The Committee at its fourteenth meeting and sixteenth meeting, held in Goa & New Delhi had taken a decision

that second hand bottles should **not** be allowed to be used for filling transfusion solutions but that manufacturers could recall their bottles from hospitals for filling.

Shri Rajadhyaksha stated that no distinction should be made in the use of second hand bottles by manufacturers and hospitals. Hospitals were indenting these transfusion fluids on the condition that empty bottles would be returned to the suppliers after the use of the contents. In actual practice, the empty bottles were left unattended in hospitals and most of them were being used for sampling urine etc. of patients, It was therefore not desirable to allow such bottles to be used for refilling. It was also mentioned that second hand bottles constituted a potential source of particulate matter in transfusion solutions and as such their use should be discouraged.

After discussion, the committee agreed that the use of second hand bottles by manufacturers of transfusions solution should be totally prohibited and that State Governments should be informed of the Committee's decision.

ITEM NO.4

Environmental conditions in tablet coating room.

The Chairman informed the committee that at the last meeting of the Port & Zonal Officers held in New Delhi in November, 1972 it was decided that as coated tablets require to be manufactured under controlled humidity conditions the coating room should be air-conditioned and dehumidified and that this requirement should be included in Schedule M to the Drugs and Cosmetics Rules. The committee agreed to this suggestion.

ITEM NO.5

Furnishing of Estimates of Narcotic Drugs for manufacture of preparations covered by Schedule III of the single convention.

The Chairman explained to the members that at present the State Drug Control Authorities supplied the total estimates of individual narcotic drugs in respect of their states for onward transmission to the International Narcotics control Board, Geneva through the Narcorics Commissioner. The Inter-national Narcotics Control Board now desire that separate estimates in respect of individual narcotic drugs included in Schedule III of the single convention -1961 (i.e. preparations for the export of which export authorisations are **not** required) should be made available by the Narcotics Commissioner along with the total Annual estimates for narcotic drugs. Schedule III of single convention 1961 includes preparations of Acetyldihydrocodeine, Codeine, Dextropropoxyphene, Dihydrocodeine, Ethylmorphine, Norcodeine and Pholcodine in quantities specified in the Schedule. As such information in respect of narcotic drugs required for the manufacture of preparations covered by Schedule III would require to be furnished by the Drugs Control Authorities in future.

Shri Shanbhogue stated that the Drug Control Administration Mysore maintain estimates in respect of individual narcotic preparations separately and that they could furnish the information, as desired by the Narcotics Commissioner. Members however desired to know whether the information required should be given in terms of the base or salt. It was agreed that this aspect should be got clarified from the Narcotics Commissioner and conveyed to the State Drugs Control Authorities and that every endeavour should be made by State Drug Control authorities to collect the information in the manner desired by the Narcotics Commissioners.

The Chairman informed the members that the Narcotics Commissioner had complained about poor lifting of Narcotic drugs

by firms and asked the members to keep a strict watch on the lifting of narcotic drugs by manufacturers located in their States. He added that to help a check in this regard, the Ghazipur factory was being asked to forward to the State Drug Control authorities a quarterly statement of the liftings of narcotic drugs in respect of individual firms.

Members desired to know the allotment of quotas of narcotic drugs for the year 1974 in respect of their States. The Chairman stated that a communication had been issued already to States to allow manufacturers to obtain 50% of the quantity lifted by them from Ghazipur factory in 1973 in respect of codeine, morphine, Ethylmorphine, Opium etc. As regards imported drugs eg. Pholcodine, Methadone and Cocaine, 50% of the quantity actually imported by them in 1973 could be allowed to firms. Manufacturers could also be permitted to import 50% of the Pethidine imported by them in 1973. In addition, firms may be allowed to lift the same quantity of Pethidine which they lifted during 1973 from M/s. Gluconate. Import of Pethidine could be allowed without insisting on forms lifting their allocations from M/s. Gluconate.

The Chairman clarified that these were interim arrangements made to prevent any shortages of preparations containing narcotic drugs and that further recommendations covering the balance of the requirements would be sent soon.

ITEM NO.6

Proposal that Drugs Inspectors may examine conditions of manufacture but should not ask for methods of manufacture, list of ingredients used etc which in certain cases constitute trade secrets.

The Chairman stated that representations had been received from the industry to the effect that Drug Inspectors while visiting manufacturing premises insist on knowing intimate details relating to

the manufacture of basic drugs and formulations and that suitable guide lines should be issued to Inspectors not to insist on asking for details which firms might wish to keep secret particularly in regard to their manufacturing techniques, yields etc.

Shri Rajadhyaksha said that certain particulars such as the composition of a preparation, the excipients, solvents and flavouring and colouring agents etc. used in the formulation and the various tests and procedures followed by firms to ensure quality of the preparation were necessary to ensure that the preparation did not pose any health hazards. This view was supported by many members of the Committee.

The Chairman pointed out that the burden of the representation from manufacturers was that intimate details were asked for even in the case of basic drugs which manufacturers consider as vital secrets. Quality control measures could be enforced without asking for details which firms may not wish to disclose.

After discussion, the Committee agreed that inspectors should be advised not to insist on the manufacturers of basic drugs to part with details which are regarded as trade secrets. In regard to manufacture of formulations, however, Drugs Inspectors could call for such details as are considered vital in the interests of the over all safety and quality control aspects.

ITEM NO.7

Proposal that in the event of a conflict between the States Government Analyst's report and or C.D.L.'s report and that of the Manufacturers' report, Manufacturers methods should be obtained and used by the Analysts.

The Committee was informed that in certain State patent and proprietary medicines had been declared not of standard quality and

that such results were a sequel to differing methods of analysis employed by the Government Analysts, vis a vis the manufacturer. It was agreed by the Committee that in such cases Government Analysts should pay due consideration to the methods of tests from the manufacturers and call for the methods if necessary before the samples are tested.

ITEM NO.8

Prohibition against altering inscriptions on containers, tablets or wrappers of drugs.

ITEM NO.9

Inclusion of a Rule in the Drugs & Cosmetics Rules to provide for confiscation of Cosmetics similar to Rules 58 and 58-A.

ITEM NO.10

Revision of the definition of the term 'Misbranded drug' and 'Adulterated drug'.

ITEM NO.11

Extent of Protection given by Sec., 19(2)(6) of the Drugs and Cosmetics Act.

ITEM NO.12

Drugs and Magic Remedies (Objectionable Advertisements) Act - Perusal of Postal Records.

Since no representative from the Drugs Control Administration Tamil Nadu was present, the Committee could **not** consider these items.

The Committee however desired that the judgments delivered in Tamil Nadu in cases relating to 'Misbranded drug' and 'Adulterated

drug' vide item 10 of the agenda should be studied by Shri Shanbhogue and Shri Rajadhyaksha, and that the copies of judgments may be made available to them by the Drugs Controller, Tamil Nadu.

ITEM NO.13

Uniform implementation of the recommendation made by the Drugs Consultative Committee, regarding standards of surgical bandages.,

Dr. Sharma stated that manufacturers in Himachal Pradesh had been asked to manufacture surgical bandages according to I.S.I. specifications where as manufacturers in certain other States were not conforming to the same specifications. He desired that uniformity of enforcement in respect of I.S.I. specifications for surgical bandages should be maintained.

The Chairman pointed out that there were certain practical difficulties coming in the way of uniform enforcement of these standards. Manufacturers were complaining that suitable cloth conforming to I.S.I. standards was not available for the manufacture of surgical bandages. In some cases manufacturers were reluctant to produce surgical bandages conforming to I.S.I. specifications because of higher cost. In consultation with manufacturers of bandages, a new set of specifications are being evolved.

ITEM NO.14

Inclusion of a provision in the Drugs and Cosmetics Rules permitting repacking of additional items by the licensing authority and levy of fee therefore.

Shri Rajadhyaksha proposed that a provision should be made under Rule 69 of the Drugs and Cosmetics Rules making it obligatory on the part of a repacker to obtain the permission of the licensing

authority to repack additional items and that a fee should be prescribed for grant of such a permission to repack additional items.

The Chairman observed that State Drugs Control authorities should discourage repacking activities. It would be advisable, he said, for a list of drugs which are absolutely necessary for being repacked, to be prepared and prescribed in the Drugs Rules. This list should take into consideration the basic drugs and tinctures which were generally required by medical Practitioners for use in their dispensaries.

Shri S.C. Shah stated that in Gujarat a list of items allowed to be repacked had been drawn and that system had worked satisfactorily.

Shri Shanbhogue stated that the question of repacking had also come up for discussion at the Southern Regional Drugs Controllers meeting.

The Chairman suggested, and the committee agreed, that a sub-committee consisting of Shri Rajadhaksha and Shri Balasubamanyan should examine the question in consultation with medical practitioner and suggest a list of items. The list of items for repacking drawn up by the Gujarat Drug Control Administration should also be taken into consideration by them. Dr. Prem K. Gupta should furnish to the sub-committee, the recommendations of the Southern Regional Drugs Controllers meeting.

ITEM NO.15

Admissibility of Colours in Pharmacopoeial and patent and proprietary medicines.

Shri Rajadhyaksha enquired whether colour can be used in Pharmacopoeial formulations and patent and proprietary medicines in accordance with the amended Rule 127 of the Drugs and Cosmetics Rules.

The Chairman clarified that Rule 127 applies to drugs not covered by the pharmacopoeia. He stated that the question whether colours and additives should be allowed in pharmacopoeial preparations was considered by the Indian Pharmacopoeia Committee at its last meeting held in June, 1973 at New Delhi. The final decisions of the Committee was that except where special mention for use of colour was made specifically in a monograph, colour should not be permitted to be added to pharmacopoeial preparations and that addition of colours should be permitted only in the case of coated tablets and grannules.

After discussion, the Committee endorsed the decision taken by the Indian Pharmacopoeia Commitee.

ITEM NO.16

Proposal that a sub-committee be constituted to study standards of certain raw materials.

Shri Rajadhyaksha stated that in Maharashtra State manufacturers were experiencing difficulty in obtaining quality raw materials such as Calcium Carbonate, Sodium bicarbonate, Zinc Oxide, Kaolin etc. which did not comply with the Indian Pharmacopoeial specifications. While they are unable to manufacture Sodium Bicarbonate conforming to the I.P. quality their Sodium bicarbonate conformed to the USP quality. Similarly, Kaolin N.F., instead of Kaolin I.P., was being permitted to be marketed in many States. He felt that the standards pertaining to such drugs in the Indian Pharmacopoeia should be reviewed.

Shri Shanbhogue stated that certain manufacturers were marketing glycerine without indicating on the label that it conformed to pharmacopoeial quality and enquired whether that 'glycerine' could be used by pharmaceutical manufacturers.

The Chairman explained that where manufacturers experienced genuine difficulties in complying with Indian Pharmacopoeial standards,

latter should be reviewed by the Indian Pharmacopoeia Committee. He suggested that the State Drugs Control authorities should examine such cases in consultation with the manufacturers concerned and furnish for the consideration of the Indian Pharmacopoeia Committee particulars of the specific drugs, the nature of difficulties, experienced by the firms, in complying with the pharmacopoeial standards and the names and address of the manufacturers.

Replying to the specific point raised by Shri Shanbhogue, the Chairman mentioned that at an earlier meeting of the Committee, it was decided that these items which were not labelled as conforming to medicinal quality but on test conformed to the requisite pharmacopoeial standards could be utilised by drug manufacturers.

ITEM NO.17

Proposal that list of ingredients used in the manufacture of cosmetics be furnished by manufacturers to the licensing authority.

Shri Rajadhyaksha stated that Food and Drugs Administration Maharashtra State called for scrutiny from Cosmetics manufacturers information regarding the formulae or the list of ingredients before grant of manufacturing licences. This procedure was adopted for assessing the usefulness of a cosmetics in the light of the claims made for it likely to cause any harmful effects. He pointed out that certain manufacturers were reluctant to supply the required information for fear of leakage of their Trade secrets. He desired that it should be provided in the rules that for the grant or renewal of a licence to manufacture cosmetics the licensing authority should be supplied with necessary information regarding the efficacy and safety of raw materials including the formulae or test of ingredients used therein for scrutiny, by the manufacturers.

The Chairman explained that in the U.S.A. the Food and Drug Administration have classified separate lists of SAFE and UNSAFE

ingredients for use in the manufacture of cosmetics and have left it to the good sense of manufacturers the choice of raw materials. In case of sophisticated items such as cosmetics, manufacturers may be reluctant to supply detailed information regarding the composition of cosmetics.

After discussion the Committee agreed that the Drugs and Cosmetics Rules should be amended making it mandatory on the part of applicants for manufacture of cosmetics to supply to the Licensing Authority information regarding the composition of the cosmetics items proposed to be manufactured including the specifications of the component ingredients.

ITEM NO.18

Applicability of the provisions of the Drugs and Cosmetics Rules to the repackers of prefumery raw materials.

Shri Rajadhyaksha stated that in Maharashtra State there were many dealers who repack scented water or 'Attor' in small bottles for religions functions, marriages etc. Repacking of similar articles of perfumery such as rose-water, 'Agarbattis' was also being done by such dealers. The Association of perfumery raw materials Trade in Maharashtra State felt that no useful purpose would be served by making the provisions of Drugs and Cosmetics Act and Rules applicable to them. He desired to know the line of action that should be taken for regulating the activities of perfumery dealers.

The Chairman felt that in the interests of safety of the products, repackers of perfumery articles should be required to take out licences under the Drugs and Cosmetics Rules as otherwise such dealers might use harmful materials. At Shri Rajadhyaksha's request, the Chairman agreed to issue suitable instructions in this regard so as to ensure uniformity of action throughout the country.

ITEM NO.19

Proposal that conditions of licence be made for maintenance of record for manufacture of Cosmetics and register of raw materials.

Shri Rajadhyaksha proposed that Rule 142 of the Drugs and Cosmetics Rules may be suitably amended to prescribe additional provisions for maintenance of record for manufacture of cosmetics and register of raw materials.

The Committee agreed to the proposal.

ITEM NO.20

Proposal that Schedule K of the Drugs and Cosmetics Rules be amended to empower the Inspector to inspect and verify records of purchase and distribution of drugs.

Shri Rajadhyaksha said that the proposal made by the Drus Controller Kerala was that the extent and conditions of exemption given under clause 5 of Schedule K be amended so as to empower Drugs Inspectors to inspect and verify the records of purchase and distribution of drugs by medical practitioners. This was important specially for regulating the activities of certain section of unethical medical practitioners.

Shri S.C. Shah also mentioned that in Gujarat some doctors were found to be in league with manufacturers of spurious drugs and the records maintained by doctors had to be checked by the State Drugs Control Organisation.

After discussion, the Committee agreed that it is necessary to provide in the Drugs & Cosmetics Rules vide entry 5 of Schedule K, that the Registered Medical Practitioner shall obtain his drugs only from a person duly licensed to manufacture, sell or distribute drugs; and that he shall maintain records of purchases of such drugs to enable

the Drugs Inspector to draw samples and to make enquiry about purchases of the drugs from the R.M.P.

ITEM NO.21

Proposal that a new definition for patent and proprietary Ayurvedic (including Siddha) and Unani drugs be incorporated in the Drugs and Cosmetics Act/Rules.

The Drugs Controller, Kerala who could not attend the meeting had written to say that the provisions of Chapter IV A of the Drugs and Cosmetics Act could not be made applicable to those Ayurvedic (including Siddha) and Unani drugs which were not covered by the authoritative books specified in the first Schedule to the Act. As such it would be difficult to regulate the manufacture and standards of such drugs unless a definition for patent and proprietary Ayurvedic (including Siddha) and Unani drugs was incorporated in the Act/Rules.

The Chairman explained to the Committee that this proposal had already been considered by the Ayurvedic and Unani Drugs Technical Advisory Board which had agreed to the proposal in principle. Suitable changes will be made in the Act/Rules in due course.

ITEM NO.22

Suggestion that uniformity in the enforcement of Drugs and Cosmetics Act and Rules relating to Ayurvedic (including Siddha) and Unani medicines be maintained by all the States.

Shri Aggarwal stated that in certain States such as Delhi, U.P., Rajasthan and Himachal Pradesh allopathic drugs are being marketed under names which give the impression that they are Ayurvedic while in Haryana, manufacturers of Ayurvedic drugs are licensed, licensing of Ayurvedic and Unani products has not commenced in other States.

Unless this is done on a uniform basis in all the States, the malpractices of the type mentioned by him cannot be checked.

The Chairman suggested and the Committee agreed that licensing of Ayurvedic and Unani medicines should be taken up expeditiously and that at the time of licensing of such medicines, the names of the products should be checked and regulated.

ITEM NO.23

Suggestion that provision should be made for destruction of drugs stocked after the date of expiry in the sales premises.

Shri Pany desired that the Drugs and Cosmetics Rules should be amended empowering Drugs Inspectors to destroy date-expired drugs that are stored in sales premises pending withdrawal by the licensee, if the licensee failed to withdraw them within a period of one month after the date of expiry. Unless this is done, there is scope for date expired goods being sold by dealers.

The Chairman stated that the present rule permitting date-expired drugs to be stored by dealers separately in a package, the top of which shall display prominently the words 'Not for Sale'. These packages may be kept on the premises till the manufacturers withdraw them from sale. Since this rule was specifically introduced at the request of State Drugs Controllers, it will look odd if the Drugs Consultative Committee were to make a suggestion that the rule should be revoked.

ITEM NO.24

Supply of information concerning firms engaged in the manufacture, sale of sub-standard/spurious drugs in inter-state Commerce.

Shri Pany suggested that for follow-up action on cases relating to suspected spurious or adulterated drugs it would be helpful if (i) State Drugs Controllers furnish on a priority basis information relating to the names and addresses of firms, validity of licences of certain units

when enquired by other State Drugs Control authorities and (2) also prepare a list of manufacturers in States on an all India basis giving all the relevant information of the type mentioned above for the guidance of all.

As for point (1), the chairman stressed the need for maintaining closs co-operation among Drugs Control authorities of various States in tracking down spurious, unlicenced and adulterated drugs and stated that all the necessary information should be supplied by any State when called upon by other State Drugs Control authorities.

As regards point (2), the Chairman pointed out that the Central Drugs Standard Control Organisation which was engaged in the preparation of a list of licensed drug manufacturers in the country on an all India basis was finding it difficult to keep it up-to-date for want of timely information from many States. Compilation of additional information, as suggested by Shri Pany, would be difficult.

ITEM NO.25

Proposal for empowering the controlling authority to inspect manufacturing and sales premises.

Shri Pany stated that at present there is no provision in the Drugs & Cosmetics Rules empowering the 'controlling authority' in a State to inspect manufacturing units. He stated that incorporation of a provision in the Rules to this effect would enable the controlling authority to carry out surprise inspections of manufacturing units and sales premises.

The committee was of the view that as long as the licensing authority of a State can inspect the manufacturing and sales establishments and satisfy himself about their activities, there was no necessity for empowering the controlling authority for the same purpose.

ITEM NO.26

Manufacture of Patent Ayurvedic Medicines.

Members were keen to know the procedure that should be followed in approving patent Ayurvedic medicines for being manufactured in their States.

The Chairman informed the committee that the Ayurvedic and Unani Drugs Technical Advisory Board had suggested that the Central Council for Research in Indian Medicine and Homoeopathy should be requested to draw up broad guidelines for the recognition of patent and proprietory Ayurvedic, Siddha and Unani Drugs. These guidelines would be finalized by the Ayurvedic Drugs Technical Advisory Board and communicated to the licensing authorities in the States. This might, however, take time. In this context the Chairman stressed the need for appointment of separate advisers in Ayurveda, Homoeopathy Unani & Siddha Systems etc. in the State Drugs Control Administrations for screening patent and proprietary medicines.

ITEM NO.27

Proposal that manufacturing concerns issue identity cards to their representatives.

The Chairman informed the committee that the State Drugs Controller, Punjab, feels that several faked representatives sold spurious drugs to traders and that to prevent this manufacturing firms should be asked to issue identity cards to their representatives.

The Committee agreed that a letter from the Drugs Controller (India) should be sent to the Associations of manufacturers in the country in this connnection.

ADDITIONAL ITEMS

ITEM NO.28

Maintenance of Night sale and Dispensing Services in the Country.

The subject of maintaining the sale of drugs and the dispensing services during the night in all important cities and towns in the country was brought for discussion at the instance of Dr. A.C. Kar, Director, Drugs Control, West Bengal on the second day of the meeting before the agenda was taken up for discussion. The discussions revealed that States such as Maharashtra, Mysore, etc. had been successfully maintaining night services to some extent while most of the States had not been able to provide such services. Chemists and druggists are reluctant to operate night servicess for several reasons such as the following :-

1. Turnover of drugs during nights is insignificant and as such not commensurate with the cost of efforts put in.
2. Most of the essential drugs required during the night are prescription drugs which require to be supplied against prescriptions of Registered Medical Practitioners. Registered Pharmacists have to be paid over-time salaries for night duty.
3. The shops were also facing the problem of pilferage of medicines during the night. Pilferage of drugs during night services is a positive problem to contend with.
4. Security risks for the staff working in the shops at night and for the drugs that are stocked are genuine, and Police protection is necessary to be provided.
5. Unless some incentive is given such as permission to charge extra amount on the sales effected during the night and also to deal in cosmetics, it might be difficult to persuade chemists to organise night services on proper basis.

The Chairman stated that in Delhi, the Super Bazars have opened branches in leading hospitals which sell drugs to public during the night on all days of the week. However for enabling the Super Bazar to maintain this service it had to be assisted in many ways. It was also pointed out that in some states efforts were made for opening of shops in hospitals which could provide night sale and dispensing services but the success of such efforts has not been significant. At one stage, he said that the question of allowing chemists an additional charge for medicines sold during the night was considered by the Ministry of Petroleum and Chemicals under the Price Control Order, but this proposal did not find favour as it was felt that such a concession could be misused by unscrupulous dealers who might adjust their day-time transactions as 'night serve' ones.

The consensus view was that closure of night sale and dispensing services will hit hard the general public, particularly, when drugs are required for treatment of emergency cases. Even though there may be some cases where the incentives may be abused by dealers, it would be desirable to allow the chemists to operate during the night with an additional 'night service charge' for sale and dispensing transactions during the night in the larger public interest.

The shops and Commercial Establisshments Act provided for opening of Chemists shops at night. However, to minimise the incidence of abuse of the incentive to be provided to dealers by Government, only selected chemists whose bonafides are well known to the State Drugs Controllers should be appointed for sale and dispensing service at night in cities and towns on the advice of the State Drugs Control authorities. Such a check could be exercised under the provisions of the Shops and Commercial Establishments Act. It was further agreed that an additional charge of Re.1 per prescription or 25% of the cost ofthe drug per prescription whichever is less, should be allowed to the Chemists for service charge as an incentive for running this essential service.

The Chairman agreed to take up the matter with the Union Ministry of Petroleum and Chemicals.

ITEM NO.29

Proposal that the Drugs and Cosmetics Act and the Rules should be amended to provide for effective quantitative control over the import, manufacture, distribution and retail sale of habit-forming drugs.

The representative of the Delhi Drugs Control Administration stated that there was no quantitative control over the import, manufacture, distribution and retail sale of habit-forming and psychotrepic drugs. The Drugs Control authorities normally did not get information regarding the quantity imported by any peson or the quantity manufactured by any manufacturer. The only measure of control that is now operative is that retail chemists should not sell such drugs without covering prescriptions from Registered Medical Practitioners. Control at the sales stage was difficult in the absence of information regarding the quantity purchased/ Possessed by the dealer. There was no restriction on inter-state movement of such drugs and as such it was very difficult to exercise any effective control. He desired that the Drugs and Cosmetics Act and the Rules should be suitably amended to provide for adequate control in this respect.

The Chairman explained to the Committee the measures that were recommended by the Sub-committee of the Drugs Consultative Committee in this regard which **inter alia** covered inclusion of a separate schedule covering psychotropic drugs in the Drugs and Cosmetics Rules; regulating their quantum of production; distribution of such drugs through only a limited number of bonafide dealers and measures to regulate the prescription of such drugs. These recommendations when finalized by the Drug Consultative Committee would be referred to the Drugs Technical Advisory Board for its consideration. He stated that the amendment of the Dangerous Drugs Act to cover the quantitative import/export of psychotropic drugs and their possession by individuals in quantities for in excess of what is needed for personal use is also under consideration of the Union Ministry of Finance.

ITEM NO.30

Proposal that the Drugs & Cosmetics Act and the Rules should be amended to provide for any Drugs Controller of any State/Union Territory to ask for information from the manufacturers/distributors of habit forming drugs situated in other States.

The suggestion of the Delhi Administration, it was noted was aimed at enabling the Drug Control authorities to obtain the necessary information for exercising control over habit forming drugs, particularly the quantities of such drugs moving in adjoining States.

(The Committee was of the view that since manufacturing firms are now supplying information about all-India distribution of habit forming drugs, no specific provisions as desired by Delhi Administration need be introduced).

ITEM NO.31

Relaxation of undue toxicity test for patent and proprietary medicines containing antibiotics meant for parenteral use.

The Chairman informed Shri Shanbhogue that draft amendments to Schedule F of the Drugs and Cosmetics Rules laying down additional tests for undue toxicity, pyrogens and histamine like substances in respect of parenteal preparations containing antibiotics was considered by the Drugs Technical Advisory Board, at its last meeting held in October, 1973, and took the decision that it would not be feasible to lay down tests for pyrogens etc. for non-pharmacopoeial antibiotic injectible preparations and that such preparations should be deemed to be "New Drugs" and their standards, including the tests for pyrogens, undue toxicity etc. should be determined by the Central Drug Control Organisation.

ITEM NO.32

Consideration of the question whether repackers come under the purview of the Drugs (Prices Control) Order, 1970.

Shri Shanbhogue stated that many repackers were disputing the applicability of the Drugs (Prices Control) Order to them and suggested that they should be brought within the purview of the order.

The Chairman said that the question will be taken up with the Union Ministry of Petroleum & Chemicals, if Shri Shanbhogue supplied particulars as to the nature of the items, the size of the packings in which the items were repacked to-gether with the end use of the items for which these were repacked in his State.

ITEM NO.33

Supplies of Drugs to Hospitals under the Drugs (Prices Control) Order, 1970.

Shri Shanbhogue enquired whether the drugs supplied to hospitals should bear the maximum retail price on the label or not.

The Chairman clarified that supplies of drugs intended to be consumed by hospitals were not subject to the Price Control Order.

ITEM NO.34

Grant of Loan Licences.

Shri Shanbhogue desired to know whether a decision had been taken to set a dead line for loan licensees to establish their own manufacturing facilities.

Clarifying the position, the Chairman stated that the decision of the Central Government was to continue the Scheme of loan licensing. He recalled that the Committee had earlier decided that loan licences

should be restricted only to parties located within the State except where special processing operations were involved. Where a loan licence was granted, it should be ensured that a competent person representing the loan licensee was present at the time of manufacture of their preparations.

ITEM NO.35

Manufacturers of Drugs to set up their own, testing laboratories.

Shri. Shanbhogue stated that manufacturers in Mysore State who did not have their own testing laboratories were required to set up such laboratories by the end of December, 1973. Since many firms were still to set up analytical laboratories, he desired that the time limit should be extended.

The Chairman clarified that it was proposed to include a rule in the Drugs & Cosmetics Rules requiring manufacturers to set up testing laboratory of their own within a specified period. This rule would be expedited. He, however, felt that manufacturing establishments which were holding import licences for import of drugs for Rs.2-3 lakhs per annum for carrying on their manufacturing activities should be prevailed upon to establish testing laboratories of their own as early as possible.

ITEM NO.36

Standards fixed for Surgical Dressings vis a vis difficulties experienced by the manufacturers in manufacturing and marketing them.

Shri S.C. Shah stated that manufacturers of surgical dressings were experiencing difficulties in complying with the standards. In particular he mentioned that ISI specifications for absorbent gauze and rolled bandages were difficult to be complied with. It was also not possible to take action against the manufacturers who were marketing material not conforming to ISI specification as these are not mandatory under the Drugs and Cosmetics Act and the Rules.

At the instance of the Chairman, Assistant Secretary to the Indian Pharmacopoeia Committee explained that standards for absorbent Cotton Wool and absorbent lint were included in the Indian Pharmacopoeia 1966 and I.P. 1955 included standards for absorbent gauze. No standards are included for bandage cloth in the Indian Pharmacopoeia. The standards for absorbent Cotton Wool and absorbent lint have been amended in the Supplement to the I.P. to accommodate the difficulties experienced by manufacturers. A major relaxation given in the case of absorbent cotton wool was in respect of staple length the average of which has been reduced from 1.5. cm to 1.2 cm.

As regards absorbent gauze and bandages, the draft standards derived from ISI specifications and circulated to the members for comments earlier, were under finalisation in consultation with the Drugs Laboratory Baroda. The intention was to examine whether further relaxation to the I.S.I. standards in respect of 'yarn count' 'warp and weight' and 'weight per unit area 'could be allowed without diluting the essential functional characteristics such as cleanliness, freedom from flourescent substances and the permissible limit of foreign matter.

ITEM NO.36

Consideration of standards for Disinfectant Fluids.

Shri S.C. Shah mentioned that the Drugs Control Administration in Gujarat was finding it difficult to take action against the manufacturers of disinfectant fluids which failed to comply with the test for Staphylococal Co-efficient as the ISI standards have no legal bearing.

The Chairman informed the Committee that revised Schedule 'O' to the Drugs & Cosmetics Rules including the test for Staphylococal Co-efficient was being introduced.

ITEM NO.37

Proposal that the first and third proviso to Rule 49 of the Drugs

and Cosmetics Rules may be deleted.

Shri Rajadhyaksha desired that the first proviso to Rule 49 providing that only these inspectors who have had not less than three years experience in the manufacture and testing of substances specified in Schedule C in a laboratory approved for this purpose by the licensing authority shall be authorised to inspect the manufacture of items mentioned in Schedule C, and also the third proviso of the same Rule providing that for the purpose of inspection of shops in any specified area any officer of the medical or public health department who is a registered medical practitioner or a graduate in science may be appointed an ex-officio Inspector, should be deleted. He agreed that those Inspectors who gained adequate knowledge over years in inspecting manufacturing premises and the techniques adopted for various manufactruing processes and had been enforcing the provisions of the Act satisfactorily so far should not be declared incompetent to inspect the premises of such products suddenly.

The Chairman informed Shri Rajadhyaksha that the question relating to the relaxation of the qualifications of Inspectors had not found favour with the Drugs Technical Advisory Board.

ITEM NO.38

Amendment of Rule 71 of the Drugs and Cosmetics Rules.

Shri Rajadhyaksha desired that in Rule 71 relating to conditions for the grant or renewal of a licence in Form 25, for the words "manufacture shall be conducted under the active direction and personal supervision of the competent technical staff", the words "manufacture shall be conducted under the active direction and personal supervision of technical staff who is competent in the opinion of the licensing authority", be substituted.

The Committee agreed to the Rule 71 being amended accordingly, and requested Shri Rajadhyaksha to suggest a revised Rule 71 for incorporation in the Drugs and Cosmetics Rules along with broad guide lines

as to the conditions for the grant or renewal of a licence in Form 25 for consideration of the Central Government.

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

PART II

ANNEXURES TO THE MEETINGS

NOTE ON ACTION TAKEN ON THE MINUTES OF THE SIXTEENTH MEETING OF THE DRUGS CONSULTATIVE COMMITTEE HELD AT NEW DELHI ON THE 28TH AND 29TH NOVEMBER, 1973.

ANNEXURE I
(Item No.2 & 3 of 17th D.C.C. Meeting)

1. General Discussions		
Shri Shanbhogue desired to know the centres where laboratory equipment could be sent for repairs/servicing. Shri Rangnekar also desired that some guidelines as to the nature/type of instruments and the sources from which these could be obtained in the country should be made available to the States.	The Chairman agreed to provide information in this respect.	The Directors/Govt. Analyst of the Central Drugs Lab., Calcutta, the Central Indian Pharmacopoeia Lab., Ghaziabad the Drugs Laboratory Baroda, the Drugs Testing Laboratory, Bangalore and the Drugs Control Laboratory, Maharashtra were requested to furnish information on the following points:- 1. Nature/type of equipment needed for use in Drug Testing Laboratory. 2. The sources of supply of such equipment including those located in 'Rupee Payment Countries' and indigenous, and, 3. The Centres where laboratory equipment could be sent for repair/servicing in the country. The Deputy Drugs Controller (India) East Zone, Calcutta has also been requested to obtain all available information from Central Drugs Laboratory on the above points. The information received from the Drugs Laboratory Baroda has been circulated. The remaining authorities concerned have been reminded. The information when received from them

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			will also be furnished to the State Drugs Control Authorities.
2.	Dr. N.C. Banerjee, Drugs Controller, Assam indicated that Drugs Control Administration in Assam was faced with certain difficulties including those relating to the distribution of narcotic drugs to firms in State.	The Chairman advised Dr. Banerjee to furnish a note in regard to the difficulties faced by the Drugs Control Administration, Assam.	Dr. Banerjee was requested to furnish the note on the difficulties faced by the Drugs Control Administration, Assam so that appropriate steps can be suggested in the matter. In reply the Drugs Controller, Assam reported that while the Drugs Control Administration, Assam is handicapped due to shortage of pharmaceutically qualified persons for the post of Drugs Inspectors, the difficulties indicated in the last meeting of the Drugs Consultative Committee regarding distribution of Narcotic Drugs to different firms, have since been overcome No further action was therefore considered necessary.
3.	**Misuse of Psychotropic Substance** At Chairman's request Dr. Gothoskar, Dy. Drugs Controller (India) and member-secretary of the sub-committee for 'exercising control over the manufacture, sale, distribution of psychotropic drugs' apprised the members of the salient recommendations contained in the sub-committee's report e.g. (1) A separate schedule	1. The Chairman agreed that control over Psychotropic drugs should be exercised as in the case of narcotic drugs. 2. The report of the Sub-committee was ready which would be circulated to the members. 3. He also stressed the need for State Drugs Control Administrations	The following action was taken:- 1. The report of the sub-committee was circulated to all members of the Committee vide this Dte. circular No.38-9/72-D dated 25.1.73, wherein in observations of the authorities were invited on the report. Summary of comments received from Drugs Controllers Kerala, Gujarat, Jammu & Kashmir,

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			Control Authorities vide this Directorate Circular No. 38-1/73-D dated the 5.4.73 and the latter have been requested to regulate the sale of these drugs e.g. Melsedin (Boots), Peposyl (Pharmed), Restyl (Cipla), Makalon (Medicare) as these preparations are similar to 'Mandrax' of M/s. Ronssel.
4. **Item No.2 (i)** **Storage conditions of Antibiotics.**	At the 13th meeting of the Drugs Consultative Committee held in Dec., 1969 at New Delhi 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 was discussed. As regards antibiotics it was observed that manufacturers do not normally recommend any special storage conditions for these preparations. To make sure that antibiotics keep well when stored in room temperature in the country, it was decided to carryout a study on the stability of antibiotic preparations stored at room temperature in different parts of the country.	The samples of antibiotics drawn and tested upto 30.1.72 in the first phase of sampling programme indicated that the antibiotic preparations, when stored at room temperature in different parts of the country, keep well and are quite stable. Before taking a final view, however, it would be better to await the next lot of samples during the second phase of the study.	The second phase of study was required to be conducted with effect from 1.4.73 vide this Dte. circular No.53-9/70-D dated 27.2.1973. Results on the 37 samples of antibiotics drawn by the State authorities in the Western Zone and sent for test by the Dy. Drugs Controller (I), West Zone, Bombay to the Govt. Analyst Drugs Control Laboratory, Maharashtra State for tests have been received. Of these 36 samples have been reported to be of standard quality and one sample relating to 'Benzyl Penicillin' 5 lakh units B.No.2-108 of M/s. Alembic has been reported to be not of standard quality for the reason that the sample contains only 3,82,700 units of 'Penicillin' as against the claim of 5 lakh units per vial.

Similarly results on 39 samples of antibiotics drawn by the State Authorities & sent for test by the Zonal Officers in East Zone Calcutta, South Zone Madras to the Drugs Lab., Baroda have been received. Of these 38 samples have been declared to be of standard quality.

One sample relating to Fortified Procaine Penicillin IP Batch No.SE-637/2DB of M/s. Glaxo has been reported to be **not** of standard quality for the reason that the sample contains 2,91,200 units per vial i.e. 78.2% of the claims of 4 lakh units per vial made on the label.

Like wise, results of 22 samples of antibiotics sent for test by the Asstt. Drugs Controller (I) North Zone to the Central Indian Pharmacopoeia Lab., Ghaziabad have been received and all of these have been declared to be of Standard Quality.

Summing up, of the 93 samples of antibiotics tested for potency at the three laboratories, 96 samples have been found to be of standard quality and only two samples have been declared as not of standard quality during the second phase of study.

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5.	**Item No.2 (ii)** **Use of Paraphenylene Diamine in hair dyes.**	Shri Rangnekar stated that manufacturers of hair dyes had represented that the dye manufactured by some foreign firms (Bayer & Hoechst) has an official melting point range of 139.5 to 141°C and that the melting range recommended by the Committee (145-147°C) should be lowered to about 140°C. It was further represented by the Industry that proper limits/standards for the purity of the dye should also be fixed.	The Committee agreed that the melting point could be fixed at 140°C if this is in consonance with the standards of leading manufacturers of hair dyes.	The question was examined further in consultation with the Commissioner, Food and Drug Administration, Maharashtra State, Bombay and the Director, Central Drugs Laboratory, Calcutta. Regarding the specification for melting point of the pure dye, the Commissioner, Food and Drug Admn., Maharashtra State has stated that so far only the German made paraphenylene dianine was available in Bombay with most of the manufacturers and that this is a good variety of paraphenylene diamine with a melting point of 145°C. As regards the standards for purity for paraphenylene diamine, the Director, Central Drug Lab., Calcutta has made enquiries from the Division of Colour & Cosmetics, Food and Drug Admn. U.S.A., M/s. Farbwake Hoechst A G, W.Germany; & M/s. Chemie Export konter, East Germany and is of the view that it is not possible at present to lay down any standards for the purity of the dye, particularly regarding the tests for freedom from toxic impurities. Inview of the position set out above, State Drugs Control authorities have

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			been asked that till such time as standards for the purity of paraphenylene diamine become available, the chemical produced by M/s. Bayer, West Germany (containing about 99% of amine of M.weight 108) having a melting point of 145°C should be used by manufacturers in the production of hair dyes & Cosmetics etc. The State Drugs Control authorities have also been requested to ensure that manufacturers, in their States, of hair dyes incorporating paraphenylene diamine comply with the following labelling requirement :- Caution - This product contains ingredients which may cause irritation in certain cases and so a preliminary test according to the accompanying directions should first be made. This product should not be used for dyeing the eye - lashes or eye-brows as such a use may cause blindness" - vide Rule 149 of the Drugs & Cosmetics Rules, (This Directorate's circular No.38-4/71-D dated 16.10.73 refers.)
6.	**Item No.2 (V)** Incorporation of Good manufacturing practices under the Drugs & Cosmetics Rules. At the twelfth meeting of D.C.C the suggestion that	The report of the sub-committee on the subject was considered. The	The report of the sub-committee relating to "Incorporation of Good Manu-

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	further conditions should be incorporated in Rules 74 and 78 to ensure good manufacturing practices and processing of drugs. The W.H.O. had prepared a draft code of good manufacturing practices. To examine the proposal in detail a sub-committee was appointed. The report of the Sub-Committee came up for discussion at the Sixteenth meeting of the D.C.C. for a decision.	Committee agreed that subject to the following changes, the report should be accepted : (i) In para 4 of Sec.VI of Annexure-I relating to 'Manufacturing Controls and Directions' vide page 6 of the Annexure, the words 'the following precautions shall be observed to prevent contamination' may be amended to read as' the following measures shall be adopted to prevent contamination or check observance of measures taken in this regard as the case may be:-' (ii) In item (iii) under para 1(a) of Annexure-II, vide page 1 of Annexure II, the words 'Capsules, dragees and powders' should be inserted between the words 'tablets' and in final containers'.	facturing practices under the Drugs & Cosmetics Rules' was revised in the light of the changes agreed to at the last meeting and the revised report circulated to all State Drugs Control Authorities vide this Dte. Letter No.38-21/72-D dated 27.7.73. The amendments agreed to by the Drugs Consultative Committee in Schedule 'U' of the Drugs & Cosmetics Rules, relating to 'Particulars to be shown in Manufacturing Records' and to the addition of a New Schedule V, regardin Good Manufacturing Practices' have been referred to the Drugs Technical Advisory Board for its consideration.
7.	**Item No.2 (vi)** Control over the Approved Testing Laboratories. The Drug Consultativc Committee at its 12th Meeting held in Cochin considered the question of exercising control over private laboratories which undertake the testing of drugs sent by manufacturers who do not have their	The report of the Sub-committee was agreed to by the Drugs Consultative Committee at its last meeting subject to the following changes being incorporated in it : i. In the 'Explanation given under Sub-rule 151 (a) at page-1 of the Annexure, the words, 'including homoeopathic drugs' should be inserted between the words 'drugs' and or 'cosmetics'.	The report of the Sub-committee relating to 'Control over licensing of approved testing lab. was revised in the light of the changes agreed upon by the Committee and the revised report circulted to the members vide this Dte. Letter No.38-21/72-D dated 27.7.73. The revised report has also been forwarded to the Govt. of India, Ministry of Health for consideration of the D.T.A.B. According

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	own facilities of testing. It was recommended that the testing labs. should be licensed under the Drugs & Cosmetics Rules and that the terms & Conditions under such licences should be examined by a Sub-committee. The Sub-committee will also recommend the amendments in the Drugs & Cosmetics Rules that will have to be made in this connection. The report submitted by the Sub-committee came up for consideration at the last meeting of the Drugs Consultative Committee.	(ii) In rule 151 (c) at page 3 of Annexure the word 'concelled' may be substituted by the word 'withdrawn' and the period of '3 years' as specified therein amended to read '2 years'. The proviso under Rule 151 (c) may be amended to fall in line with similar provision relating to manufacturing & sales licences under the Drugs & Cosmetics Rules as amended by the Govt. of India Min. of Health & F.P. Notification No.X-11014/12/72-D dated 5.6.72 and provide for levy of additional fees on a monthly rate for a period of six months from the date of expiry of the approval. If this is done, a proviso will have to be appended in this regard to sub-rule 1 of Rule 151 (a) and the additional fees payable per month specified separately for renewal of the approval in the case of approval for testing of (i) drugs specified in Schedule C & C1 and (ii) other drugs & cosmetics. (iii) In para 'g' under Rule 151 (D) at page 4 of the Annexure, the words 'as well as the licensing authority is located' should be deleted in view of the decision taken to delete Rule 151 (K). (iv) Sub-clause 2 of Rule 151 (J) at page 6 of the Annexure may be recast	to the proposal contained in the report, the desired objective of exercising necessary control and check over testing laboratories is sought to be achieved by prescribing the conditions of approval of such laboratories under the Drugs & Cosmetics Rules. A draft amendment regarding 'Approval of Testing Laboratories' has been proposed. Consequental amendments to Rules 71, 71-A, 74-A, 74-B, 76,78,85-E and 139 have also been proposed for consideration of the D.T.A.B. The necessary draft amendments proposed by the Sub-committee to Schedule M, regarding minimum requirements of space and equipment for manufacture of tincture and disinfectants, as agreed to by the Committee have been referred to the Drugs Technical Advisory Board for its consideration.

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		so as to provide for appeal to the State Govt. (v) Rule 151 (K) at page 6 of the Annexure should be deleted. It was also agreed that the report of the Sub-committee should be revised in the light of the above changes and the revised report circulated to the members.	
	Item No.3 (c)		
8.	Incorporation of additional provisions in Schedule M to the Drugs & Cosmetics Rules in respect of space and equipment for the manufacture of (i) Absorbent Cotton Wool (ii) Tinctures (iii) Acids, (iv) Fine Chemicals (v) Disinfectants and (vi) Insecticides.	The Committee noted the Sub-committee's recommendation that it would not be possible to lay down the minimum requirements in respect of space and equipment for the manufacture of Acids, Fine Chemicals, and Insecticides as these categories included a number of items of varying composition and the space and equipment required for their manufacture would depend upon the nature & composition of the items to be manufactured, the process employed for manufacture and the size of manufacture. The Committee also took note of the Sub-committee's recommendation that it would also not be practicable to lay down any requirements in respect of minimum equipment and space under Schedule M for manufacture of Absorbent Cotton Wool in view	

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		of different type of equipment being in use by different manufacturing units in the country, the various processes involved etc. Draft amendments proposed by the Sub-committee to Schedule M regarding minimum requirements of space & equipment for manufacture of Tincture and Disinfectants were agreed to by the Committee.	
	Item No.4 (i)		
9.	Progress of enforcement of Drugs Rules relating to Ayurvedic & Unani drugs, homoeopathic drugs and Cosmetics.	The progress was reviewed & the following decisions taken :- 1. Rajasthan which had **not** enforced Ayurvedic & Unani and homoeopathic Rules should take early steps for their enforcement. 2. States which have not enforced the Rules for control over cosmetics should do so as early as possible.	The decisions were brought to the notice of the State Drugs Control Authorities vide this Directorate circulr letter no.38-22/72-D dated 27.2.1973.
	Item No.4 (ii)		
10.	Sale of Ayurvedic and Unani drugs, (manufactured in States where Rules for control of Ayurvedic & Unani medicines have not been enforced) in States where the Rules have been brought into force.	All States should take steps to enforce the rules for Control of Ayurvedic and Unani medicines as early as possible. However, till such time as the enforcement of these rules in certain States is brought into force, The Ayurvedic medicines manufactured	The decision was brought to the notice of the State Drugs Control Authorities vide this Directorate Circular No. 38-22/72-D dated 27.2.1973.

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		by bonafide Ayurvedic firms in such States should continue to be permitted to be sold in other States, Where the Rules relating to quality control over Ayurvedic and Unani drugs have already been brought into force.	
	Item No.6		
11.	Course of action that should be taken on reports of samples of drugs manufactured by a licensee situated within other State than the one in which the sample is seized and declared sub-standard by the Govt. Analyst.	(i) The batch which was reported as not of standard quality on test should be withdrawn from the market. (ii) In case it is found that the reference samples with the manufacturers are of standard quality and the drugs moving in the market are not, the Drugs Controller of the State where the drugs are moving may refer the case to the Zonal Officer for making suitable investigations.	the decision has been brought to the notice of all State Drugs Control Authorities vide this Directorate Circular No.38-22/72-D dated 27.2.73.
12.	**Item No.10** Powers of Inspectors to draw samples of raw materials.	Raw materials are deemed to be 'drugs' within the meaning of Sec.3(g)(i) of the Drugs & Cosmetics Act and the Drugs inspectors can draw samples of raw materials.	The position was intimated to the State Drugs Control authorities vide this Dte. Circular No.38-22/72-D dated 27.2.73.
13.	**Item No.11** Prosecution of Manufacturers by the States where the Offences are Committed/ detected.	Notwithstanding the convention that action against manufacturers should be normally taken by the Drugs Controller of the State in which the manufacturer is located, circumstances may	The decision has been brought to the notice of the State Drugs Control Authorities vide this Directorate circular No.38-22/72-D dated 27.2.73.

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		arise in specific cases where action in the State where the offence was detected may have to be initiated. Similarly, in cases where the offence had assumed a certain measure of local importance, the normal convention in regard to prosecutions or other means may have to be bypassed and the States where the deficiences or offence were detected mayhave to take action.	
14. **Item No.12**			
	Particulate matter in transfusions-use of second hand bottles.	Second hand bottles should not be allowed to be used for filling transfusion solutions. There should, however, be **no** objection to manufacturers of transfusion solutions being permitted to recall their bottles from hospitals and filling them.	The decision has been brought to the notice of the State Drugs Control Authorities vide this Directorate Circular No.38-22/72-D dated 27.2.73.
15. **Item No.13**			
	Issue of Press Release	Where public health was in geopardy, press-notes can be issued in terms which could warn medical profession and the public that suspicion has been cast on the quality/safety of a product and that pending confirmation of this suspicion and in the interests of public health, the withdrawl from use of the product is advisable.	The decision was brought to the notice of the State Drugs Control Authorities vide this Directorate Circular No.38-22/72-D dated 27.2.73.

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16.	**Item No.14** Repacking of Schedule C(1) drugs.	The Committee reiterated its earlier decision that there is no specific provision in the Drugs & Cosmetics Rules for repacking of Schedule C1 drugs and that as such repacking of Schedule C(1) drugs should not be permitted.	The decision was brought to the notice of the State Drugs Control Authorities vide this Directorate Circular No.38-22/72-D, dated 27.2.73.
17.	**Item No.15** Approval of an item for manufacture which is official and appears to be sub-therapeutic.	The following decisions were recommended for being adopted as guide-lines:- (i) In case of preparations where the pharmacopoeia lays down the 'Usual strength' and also specified the dose range, the preparations marketed in the usual strength or in a strength which falls within the dosage range specified therein, may be deemed to be pharmacopoeial. (ii) Where the pharmacopoeia prescribes a dosage range for a preparations without specifying any usual strength, the preparation should be in a strength which shall not be lower than the lowest dosage given in the pharmacopoeia. (iii) Where a preparation is marketed in a strength lower than the dose specified in the pharmacopoeia and the manufacturer takes the plea that the preparation is meant for paedeatric	These decisions were circulated to the State Drugs Control authorities vide this Directorate Circular No.38-22/72-D dated the 27.2.1973.

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		use, evidence in support of marketing a preparation in lower strength should be adduced by the manufacturer. The paedeatric dosage given in the Indian Pharmacopoeia or the National Formulary of India should be considered as guide lines by the administration. In addition, the manufacturer of such preparations should also be required to show a distinguishing legend on the label reading 'For use of children only'. (iv) In case of all preparations covered by the pharmacopoeias irrespective of whether the 'Usual strength' is prescribed or not, where preparation marketed by manufacturer contain drugs in quantities higher than the maximum dose prescribed in the pharmacopoeia, such a preparation should be considered as pharmacopoeial preparation.	
18. **Item No.16** Practicability of enforcement of the latest amendment to the Drugs & Cosmetics Rules regarding retail packing of all drugs by manufacturers.		Loose sale of tablets and capsules from bulk containers provided scope to unscrupulous dealers to substitute drugs and as such it would be necessary that all drugs should be made avilable in retail packing. The enforcing authorities should remain firm in implementing the amended Rule 105.	The decision was brought to the notice of the State Drugs Control Authorities vide this Directorate U.O. No.38-22/72-D dated 27.2.1973.

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19.	**Item No.21**		
	Proposal that Acetyl Salicylic Acid Tablets I.P. should be required to be sold in tin containers to prevent hydrolysis of the product during transportation or shortage.	1. While hydrolysis of tablets cannot be totally prevented it was possible to minimise this process if manufacturers took adequate precautions such as :- (a) dry method grannulation (b) avoiding the use of excipients which are hydroscopic. (c) carrying out the tableting activities under dehumidified conditions, and, (d) adopting moisture-proof containers and closures with desicating agents lodged inside separately. 2. A leading manufacturer of reputable quality of Acetyl salicylic acid tablets has submitted a note in this connection and the **chairman** promised to circulate the note to the members. 3. If despite these precautions the products are found to deteriorate, manufacturers should be compelled to indicate a date of expiry of potency.	1. The decisions taken were brought to the notice of the State Drugs Control authorities vide this Directorate circular No.38-22/72-D dated 27.2.73. 2. A note on the control on free Salicylic Acid in Aspirin tablets was also circulated to the State Drugs Control authorities vide this Directorate Circular No.38-22/72-D dated the 25.1.73, so that the precautions suggested in the note are enforced on the manufacturers of Aspirin tablets. The State Drugs Control Authorities were also requested to check frequently the quality of such tablets through samples taken from the open market.
20.	**Item No.22**		
	Additional Items : Reactivisation of State Drugs Advisory Boards.	(i) The State Drugs Advisory Boards should be constituted where such	1. The decision of the Drugs Consultative Committee in this regard

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		Boards have not been constituted and States should make sure that they meet regularly. Ministry of Health would be approached to address the State Government in the matter setting out the composition and functions of such Boards.	was circulated to all State Drugs Control authorities vide circular No.38-22/72-D dated 27.2.73. 2. The Govt. of India, Ministry of Health and Family Planning were also requested to write to the State Government in the matter. 3. The Govt. of India, Ministry of Health & Family Planning write to the State Governments vide their circular No.X.19012/1/73-D dated the 8.3.73 to expedite the formation of the State Advisory Boards where no such Boards had been constituted and also to ensure that they meet regularly. The composition and functions of the Boards have been set out to the States in the letter. The latest position is that State Advisory Boards exist in Maharashtra, West Bengal, Andhra Pradesh, Assam, Mysore, Punjab, Rajasthan, Tamil Nadu, Bihar, U.P. Delhi Administration, Orissa Gujarat, Himachal Pradesh and Pondicherry or that the Boards are being reconstituted. No Boards exist in Arunachal Pradesh, Andaman and Nicobar Islands, Haryana and Nagaland. Interim replies have since been received from the latter States

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			to the Govts. communication that the matter is under their consideration.
		2. At the instance of Shri Rangnekar it was also agreed that proceeding of the Drugs Consultative Committee should also be furnished to the State Governments in future. Resolutions passed and the salient recommendations made by the committee would also be circulated to State Governments.	At the instance of this Directorate proceedings of the Sixteenth meeting of the Drugs Consultative Committee were forwarded by the Ministry of Health and Family Planning to all State Governments vide their letter No.X.19013/1/73-D dt.25.4.73. In particular the attention of the State Governments were drawn to the two resolutions namely (1) relating to establishment of mobile anti-spurious squads with financial assistance from the centre and (ii) exercising control over the manufacture, sale and distribution of Psychotropic drugs, as recommended by the Committee.
21. **Item No.23** Use of Screw Caps for Homoeopathic medicines.		In view of shortage of good quality cacks for bottles of Homoeopathic medicines, some foreign manufacturers were using screw caps made of plastic in place of corks. It would be in the interest of the Homoeopathic Industry in the country to use similar screw caps for their products.	The decision had been conveyed to the State Drugs Control authorities vide this Directorate circular No.38-22/72-D dated 27.2.1973.
22. **Item No.24** Loan Licences for manufacture of fine chemicals.		Firms should set up their own units for manufacture of basic chemicals,	The decision taken circulated to the State Drugs Control authorities vide

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		wherever imported and canalised items were required for manufacture of fine chemicals against loan licence, no recommendations should be made by the State Drugs Control authorities in favour of loan licences. Instead, increased allocations may be made in favour of the actual users to help them utilise their capacities to the full. There should, however, be no objection to granting loan licences for fine chemicals if the raw materials involved are entirely indigenous.	Circular No.38-22/72-D dated the 27th February, 1973.
23. **Item No.25** Discontinuance of Abortifacient preparations containing Ergot.		Abortifacient preparations containing Ergot were harmful and dangerous. In West Bengal all the manufacturing licences granted earlier for such preparations had been withdrawan. All States should implement action in this regard in the same manner as West Bengal.	The devision was brought to notice of the State Drugs Control authorities vide this Directorate Circular No.38-22/72-D dated 27.2.73. The State Drugs Control authorities in Maharashtra Gujarat, Haryana and Delhi Administration have since discontinued abortifacient preparations containing ergot from being manufactured in their respective states.
24. **Item No.27** Control over advertisements of diseases under the Drugs and Magic Remedies (Objectionable advertisements) Act, 1954.		The Committee agreed that details about malpractices (instances of the type where doctors advertise in newspapers that they cure the incurable diseases covered by the Schedule to the Drugs and Magic	The State Drugs Control authorities were requested vide this Directorate Circular No.38-2/73-D dated the 23.2.73 to furnish details of advertisements/malpractices of this type so that these may be brought to the

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		Remedies (Objectionable Advertisements) Act, 1954 without naming the drugs, or move from station to station for consultation by the public in this regard, or where they make false claims to make money by suggesting treatment for incurable diseases or where suggestions for treatment of venereal and sexual diseases that fall within the purview of the Act, are offered through correspondance newspapers and journals which are likely to result in self medication by innocent people) should be collected from the States Drugs Control authorities and the Union Ministry of Health should be apprised of the activities and the inability of the State Drugs Control Organisations to take any action under the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 and that it would be advisable for the Central Government to examine what action can be taken to regulate such activities.	notice of the Ministry of Health. A number of advertisements were furnished by the Drugs Control authorities in Goa, Tamil Nadu, Gujarat, Maharashtra, and Asstt. Drugs Controller, South Zone, Madras. These advertisements were brought to the notice of Health Ministry to enquire what further action can be taken to curb such activities. The Ministry of Health examined the matter in consultation with the Union Ministry of Law and Justice. The Ministry of Law has relevated that the Drugs and Magic Remedies (Objectionable Advertisements) Act,. 1954 is not expected to comprehensively provide for this problem as it is a matter essentially of professional conduct and etiquette, but has suggested that Section 20-A of the Indian Medical Council Act, 1956, which was inserted in the Act in 1964, gives adequate powers to the Council to meet the etiquette,requirement of the problem raised by the Drugs Control authorities. The Ministry of Law is of the view that in the circumstances, it would be for the council to take appropriate steps under the Law. Section 20-A of the Indian Medical Council Act as amended in 1964 is

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			reproduced below for information. 1. The Council may prescribe standards of professional conduct and etiquette and a code of ethics for medical practitioners. 2. Regulations made by the council under sub-section (1) may specify which violations thereof shall constitute inferior conduct in any professional respect, i.e. to say professional mis-conduct and such profession shall have effect not withstanding anything contained in any law for the time being in force. Since the misleading advertisements referred to by the State Drugs Control authorities are from medical practitioners of the Ayurvedic, Unani, Siddha systems, it is doubtful whether professional conduct of such practitioners can be regulated by the Indian Medical Council particularly when such practitioners are **not** covered in Medical Council Act. Health Ministry has been requested to point out this aspect to the Union Ministry of Law and Justice and seek their advice further in the matter.