

**MINUTES OF THE 20TH MEETING OF THE DRUGS
CONSULTATIVE COMMITTEE HELD AT NEW
DELHI ON THE 4TH & 5TH JULY, 1978**

The Chairman, Dr. S. S. Gothoskar, welcomed the members present at the Twentieth meeting of the Drugs Consultative Committee. He said that the Committee which used to meet normally once every year was now meeting after two years. Due to certain unavoidable circumstances, the Committee could not meet in 1977 and even the meeting scheduled to be held in May had to be postponed as he had to go to Geneva for

attending a meeting of the World Health Assembly. He, however, hoped that the next meeting would be held within a year if not earlier.

The Drugs Consultative Committee, he said, is an important Committee since it is concerned with the uniform administration of the Drugs & Cosmetics Act in the country. He welcomed the new members and said that the relations between the Central Drugs Standard Control Organisation and State Drugs Control Organisation had always been cordial. On behalf of the Central Drugs Standard Control Organisation, he assured the members of the fullest co-operation and assistance that is possible.

He spoke of the misfortune of the committee in losing from their midst a great stalwart in the field of Drugs Control, namely, Dr. M. K. Rangnekar, Commissioner, Food & Drug Administration, Maharashtra. Dr. Rangnekar was a member of the Drugs Consultative Committee for 17 years and his contribution to the deliberations of the committee had been substantial. The Committee would miss his humorous and effective interventions. The committee was also sad to learn of the passing away of Shri J. N. Barbora, Asstt. Drugs Controller, Assam. The committee observed a minute silence in the memory of the two departed souls. It was agreed that a suitable condolence messages should be sent on behalf of the Committee to the bereaved families. The Chairman made the following salient points in his opening remarks :-

1. The 'New Drug Policy' has been announced by the Govt. of India. This policy envisaged a substantial expansion of the drug industry. The total output of the Drug Industry was expected to increase from Rs.900 crores to Rs.1900 crores during the next five years. This expansion would naturally result in a greater responsibility being cast on the shoulders of the State Drug Control authorities and the Drugs Control machinery both in the States and the Centre would have to be geared up to discharge this increased responsibility. The State Drug Control Organisations would have to expand and for this it was necessary to make provision in the Sixth Five Year Plan of the States. The Chairman assured the members that when these State Plan proposals came before the Planning Commission, the Centre would do its utmost to see that these provisions are agreed to. He informed the members that the Central Drugs Control Organisation has proposed a centrally sponsored scheme in the Sixth Five Year Plan for extending financial assistance to the States for expansion of the State Drugs Control Administrations and hoped that this scheme would be agreed to by the Planning Commission and the Ministry of Finance.

2. During the Fifth Five Year Plan a scheme for extending financial assistance to States for setting up combined food and drug laboratories or augmenting the testing facilities for analysis of drugs was started and this scheme was being continued during the Sixth Five Year Plan. The Chairman pointed out that the States had been requested time and again to furnish quarterly returns of progress and expenditure in respect of this scheme but these returns were not being received regularly from many States and not at all received from some States. He stressed that submission of the timely returns was necessary since it strengthened the Centre's hands while discussing the Annual

allocations with Planning Commission. He therefore requested the members to see that the quarterly returns were submitted regularly and in time.

3. There is a persistent criticism that there is a Plathora of drug preparations being marketed in the country, some of which have doubtful therapeutic value and in some cases positively harmful. Although there is a provision permitting the Licensing Authority to screen formulations from the angle of therapeutic rationale, yet sufficient use of provisions was not being made and all kinds of drug formulations were being licensed. The Central Drugs Control Organisation has issued circulars on several types of combinations which are considered to be unnecessary and in some cases positively harmful but uniform action on these circulars was not being taken. The Chairman said that it is the responsibility of all concerned to see that irrational combinations are not allowed to be marketed. To facilitate screening of irrational formulations, he recalled that it was recommended earlier that the States should set up a screening committee consisting of one pharmacologist, a professor of Medicine, a Pharmacist and an Analyst and reiterated that action should be taken in this regard, if not already.

4. Another area of concern was the commencement of manufacture of biological diagnostic reagents by a number of small units. During the last few years complaints have been received that these reagents are not of standard quality and do not give reliable results. He requested that greater attention should be paid to such units by the licensing authorities and if their products were found to be unreliable then the manufacturing licences granted to them should be cancelled.

5. The Chairman drew the attention of the members to the amendment to the Drugs and Cosmetics Rules in the final form requiring all manufacturers to have their own testing laboratories and said that due to the large number of representations received, this amendment had been kept in abeyance pending consideration by the committee. This item has therefore been included in the agenda and the committee might take a decision in the matter.

6. The problem of sub-standard and spurious drugs continued unabated. Regarding sub-standard drugs the Chairman felt that the action that was being taken was for form adequate. Even in cases where the drugs were declared sub-standard for major defects, the firms had been let off with a mere warning. He felt that such mild action did not deter the firms from manufacture of sub-standard drugs and advised the members to take more stringent action such as suspension of licence or cancellation of licence for that particular item which had repeatedly been found to be not of standard quality.

7. During the last meeting of the Drugs Consultative Committee, the question as to what action should be taken in cases of reports of untoward reactions and particularly of fatal reactions was discussed. It was decided that the State where this reaction was reported would furnish certain vital information in a proforma which had been devised for the purpose. It was understood that in most cases the reporting States did not furnish the necessary information, in the absence of which no effective action was possible. He therefore stressed the need for furnishing the information required under the proforma as

quickly as possible to the concerned Zonal Officers and the Central Drugs Control Organisation at the Headquarters so that the complaint could be investigated and appropriate action taken without loss of time.

8. It had also come to our notice that approved laboratories did not furnish full reports on the raw materials tested by them. The laboratories carried out only a few tests and declared the material to be of standard quality in so far as these tests were concerned. This was most unsatisfactory. Approved laboratories should be required to furnish detailed and complete reports on all raw materials and finished products tested by them. In case the laboratories did not have the necessary facilities to perform all the prescribed tests, they should not be approved.

9. The Chairman informed the members that the publication "Drugs and Cosmetics Act and Rules" was being reprinted and very soon they would have an up-to-date copy of this publication.

10. The Chairman then sought the assistance of the members in compiling the 'All India List of Licensed Drug Manufacturers' and requested them to furnish 100 copies of the list of licensed manufacturers in their respective States as on 1-1-78. This would facilitate compilation of the All India List of Licensed Drug Manufacturers, which could then be circulated to all State Drug Control authorities and the All India Chemists & Druggists Association for guidance. The members agreed to the request made by the Chairman.

The Chairman then invited general comments from members briefly highlighting the achievements / activities in respect of their States before taking up the agenda proper. Earlier the copies of the Resume on the activities of the State Drugs Control Administration as furnished by the members, were circulated amongst them.

ASSAM

Dr. Banerjee referred to the case of death of a patient in a Railway Hospital due to suspected adverse reactions of some drug or drugs administered to him. Several drugs had been given to the patient. The stocks of these lying with the hospital were seized and samples sent for test 4 or 5 drugs were found sub-standard. However, there was considerable delay in obtaining the Test Reports. The relatives of the patient wanted to have copies of the test reports so that they could see the of manufacturers. Dr. Banerjee wanted to know what should be done in such cases.

He thanked the Central Government for extending assistance to set up a drug testing laboratory in Assam. He pointed out that because of shortage of cement, much expenditure could not be incurred on this Scheme during the V Plan. Efforts will be made to complete the laboratory during the VI Plan if necessary assistance is continued to be given. Replying to the points raised by Dr. Banerjee, the Chairman said that he would like to have detailed information on the drugs under question in the prescribed proforma, so that further detailed investigations could be made in the matter and other States could

also be alerted if necessary. He told Dr. Banerjee in all fatal cases and cases of serious adverse reaction the Analysts should be apprised the circumstances of the case and requested to expedite the Test Report. He, however, felt that copies of the Test Reports should not be given to the relatives of the affected patient, they could be produced only in the court if the Court so orders. A drug on analysis may be reported sub-standard on account of its having a lower content of the active ingredient but it may not be the cause of death. It has, however, to be determined whether a drug is toxic or not. The information contained in the proforma is helpful to arrive at this conclusion.

DELHI

Dr. Sharma stated that so far as Delhi Drug Control Administration was concerned a post of Deputy Drugs Controller had been filled up. Their inspectorate had been able to unearth 5 cases of spurious drugs moving in the market. Their administration implemented the Price Control Order in the Union Territory rather strictly. There had been some adverse criticism that drugs supplied by Govt. hospitals and dispensaries were spurious. Special surveys were carried out in this regard and none of the samples taken from these hospitals / dispensaries was found to be spurious. Delhi Administration has allotted 2 acres of land for construction of a testing laboratory and a scheme for strengthening Drugs Control in Delhi has already been submitted to the Administration.

GUJARAT

Shri Shastri informed the Committee that Rs.60 lakhs have been provided in the Rolling Plan of the State for expansion of the Drugs Control Administration. A special provision of Rs.1 lakh has been made for setting up a statistical branch.

He stated that expenditure returns in respect of purchase of equipment for the laboratory are sent by him regularly. There is however delay in receipt of the figures of expenditure on construction of the laboratory wing, from the P.W.D.

Shri Shastri said that whenever any drug manufactured in their State is found to be sub-standard due to major defects, penalties such as suspension or cancellation of the licence or withdrawal of the permission to manufacture the particular product complained of, was resorted to.

Shri Shastri pointed out that in the case of some approved laboratories they could not carry out certain tests for want of certain sophisticated equipment. He suggested that such laboratories should be permitted to use the equipment in Universities etc.

PUNJAB

Dr. Nar stated that he would like to have Centre's technical help in strengthening the State's laboratory. A team was to visit the State's laboratory and make recommendations regarding the manner in which it could be strengthened but the visit of

the team had been postponed. Dr. Pabrai, Director, Central Indian Pharmacopoeia Laboratory, Ghaziabad intervening at this stage said that he was involved with the visit and he assured Dr. Nar that the team would go over to his State as soon as possible.

Dr. Nar requested the Chairman that when circulars were issued from the Centre requiring enforcement of any Drugs Control measure, a date should be fixed by which all States should enforce the same. Manufacturers in his State who are required to comply with any such measure usually complained that manufacturers in adjoining States were not implementing it.

MEGHALAYA

Shri Shullai, Drugs Inspector of State states that Meghalaya is a small state. He mentioned the set up of the Drugs Control Organisation in the State and stated there is no laboratory attached to the Organisation in the State. Arrangements existed with Central Drugs Laboratory for testing samples. He expressed his difficulty in obtaining the Indian Pharmacopoeia and the Drugs and Cosmetics Act and Rules. He also said that Centre had extended assistance for purchase of equipment worth Rs.2 lakhs during 1976 for Pasteur Institute, Shillong. Replying to Shri Shullai, the Chairman said that both the publications were under print and would be available soon.

MADHYA PRADESH

Dr. P. C. Sen stated that State Government have decided to separate Food and Drugs Department from Health. The set up of the administration would be on the pattern adopted by the Food & Drug Administration Maharashtra. A high powered screening committee had been appointed to screen drug formulations which was their main problem. At present records were not being maintained systematically in the State which often constituted a lacuna in prosecution. A systematic record system was being evolved in the administration.

TAMIL NADU

Shri Narasimhan, Joint Drugs Controller, Tamil Nadu stated that the Drugs Control Wing had been transferred to Public Health Deptt. in the State and the Director of Public Health is the Drugs Controller. He gave details of the set up of the Drugs Control Organisation in the State. He mentioned that they had constructed their own laboratory for testing of samples and would be able to utilize the whole building by the end of the year. He stated that special work like investigation of illegal sales of Narcotic drugs had been undertaken in the State and a number of cases have been unearthed. Instances of drugs pilfered from Govt. hospitals had come to the notice of their administration. He spoke of the possibility of a clandestine racket on an inter state levels. He stated the Government were thinking in terms of bringing out an Act requiring the embossing of the name of the State on the lakhs of the drugs and on individual tablets. He enquired from the Chairman whether such embossed tablets would attract central excise duty.

The Chairman stated that this is a matter for the Central Excise Authorities to consider and the Govt. of Tamil Nadu may make a reference to the Ministry of Finance in the matter.

UTTAR PRADESH

Dr. Banerjee, Drugs Controller, Uttar Pradesh stated that in his State Ayurvedic and Unani preparations had been brought under the purview of the Drugs & Cosmetics Act but not Homeopathic drugs. He mentioned difficulties in recruiting Inspectors with experience in the manufacture of C & C drugs and wanted that the qualifications prescribed for recruitment of Drugs Inspectors should be relaxed. He stated that Drugs Control Admn. in the State had been bifurcated and a new Drugs Controller for Ayurvedia had been appointed. He pointed out that there is no provision in the Drugs & Cosmetics Act for misbranded Ayurvedic drugs. He stated that the names of Ayurvedic drugs should not resemble those of allopathic drugs. He also stated that some firms had been marketing Ayurvedic Injections even prior to Ayurvedic drugs being brought under Control of the Act and some check should now be exercised with regard to their safety and efficacy. The manufacture of these Injections is at present being licensed as Schedule C drugs.

He also stated that the testing laboratory with Central assistance has to be built in Varanasi. As the construction of the building was taking time, the administration should be permitted to utilize assistance for purchase of equipment.

The Chairman informed Dr. Banerjee that rules were being amended to facilitate recruitment of Inspectors authorized for inspection of establishments manufacturing Schedule drugs. He also informed him that the Drugs & Cosmetics Act was being amended to include a definition of Misbranded Ayurvedic drugs and lay down the penalties for manufacture and sale of such drugs. The Chairman, however clarified that item 12 of Schedule C covered modern drugs only and not Ayurvedic Injections.

WEST BENGAL

Shri Sen Gupta, Director of Drugs Control, West Bengal stated that the Drugs Control Department in West Bengal is independent which is now headed by a non-medical person. A comprehensive scheme for reorganization of the Analytical Laboratory was submitted to the West Bengal Govt. and the Govt.'s sanction has been received. Funds for purchase of equipment and staff have been sanctioned. A scheme for reorganization of the administrative set up on the pattern of Gujarat and Maharashtra is being prepared for consideration of the State Government. Shri Sen Gupta voiced his concern over the death of pharmacists in the State. To meet the needs of the State for pharmacists three vocational institutions imparted employment oriented training in pharmacy and ran courses on the lines as prescribed by the Pharmacy Council of India. But these institutions are not recognized by the Pharmacy Council of India. The future of these pharmacists unless they are registered would be in jeopardy. So the Pharmacy Council of India is being approached to give registration to these Pharmacists.

Shri Sen Gupta referred to the expansion of the Drug Industry during the next five years as envisaged by the Chairman and desired that one-third of the investment in the Public Sector should take place in his State. Shri Sen Gupta stated that in accordance of an earlier decision of the Drugs Consultative Committee abortifacient preparation had been banned in West Bengal but preparations continue to be manufactured in some other States and find their way into West Bengal also. He desired uniformity of enforcement in this respect.

Shri Sen Gupta also mentioned that Homeopathic Injections labeled with the words for oral use were being marked and desired a decision to be taken in this regard.

The Chairman asked Shri Sen Gupta to write to him about the particulars of firms which were marketing abortifacient preparations in other States and promised to take up the matter with the concerned States. AS regards manufacture and marketing of Homeopathic Injections in the manner described by Shri Sen Gupta, the Chairman stated that a decision had already been taken that this should be stopped. Shri Narsimhan said at this state that there was a recent High Court Judgement in Madras regarding homeopathic injections. The Chairman requested Shri Narsimhan to send a copy of the Judgement to him for his information.

PONDICHERRY

Dr. Sambasivam, Commissioner Food & Drugs Admn. Pondicherry stated that in this territory the Community was well educated and was fully aware of the dangers of use of spurious drugs. Besides the inspectorate staff kept a strict vigil over movement of such drugs. He stated that they did not have testing facilities of their own and depended upon the facilities offered by the State of Karnataka. He requested the Chairman to consider extending financial assistance to his territory for setting up their own laboratory during the 6th Plan.

KARNATAKA

Dr. Lalitha Michel, Director Indian System Medicines and Homeopathic, Karnataka stated that Ayurvedic and Unani Inspectors were being appointed in the State. Steps had been taken to strengthen the laboratory for Ayurvedic drugs and a scheme had been submitted to the State Govt. in this regard. She expressed her difficulty in dealing with persons who were registered in the State Registers on the basis of more experience and applied for grant of licences, for manufacture of drugs under the provisions of Rule 157(2)(d). These persons had no basic knowledge and could not even identify the raw materials. She suggested that Rule 157(2)(d) should be deleted.

She stated that Ayurvedic medicines and medicines for veterinary use were being sold without any licence. This needs to be checked.

She also stated that some people brought some powder from outside the State and they wanted licence to tablet the powder. She sought the Committee's guidance in the matter because in her opinion the persons applying for licence were ignorant about the nature of the raw material and were incompetent people. Replying to Dr. Lalitha Michel, Chairman said that there is nothing wrong with Rule 157(2)(d). So long as a person is a genuine vaid or Hakim and had four years experience, he could be approved as competent technical staff. The Chairman also suggested that a panel of experts as in the case of Maharashtra and Gujarat should be appointed to judge the bonafides of the applicant for approval as competent technical staff and only after the panel clears the person as fit, he should be approved.

In regard to veterinary drugs, he said, an amendment to the Act is under consideration and the point raised in this regard would be covered by it.

The Chairman also clarified that if a person applying for a licence to manufacture drugs was not in a position to convince the licensing authority about his technical competence, the Licensing Authority is within his right to reject such an application.

KERALA

Shri P. M. Varkey, Drugs Controller, Kerala stated that there were separate departments under separate authorities for control over food and drugs. There were separate laboratories also for testing of samples of Food & Drugs. He desired that Central assistance should be granted to his State also for expansion of the Drug Laboratory. He also informed the Committee that an Intelligence Cell was being set up in the State. He stated that indigenous manufacturers of Ayurvedic drugs in the State wanted a Malayalam translation of the Drugs and Cosmetics Act and Rules and asked the Chairman whether this could be done. In the vaccine institute in the State, conditions are not quite satisfactory and needed improvement, he said.

Replying to Shri Varkey, the Chairman suggested that with regard to the translation of the Drugs and Cosmetics Act and Rules thereunder he could perhaps consult his legal department. About the conditions obtaining in the Vaccine Institute, he suggested that a panel should be set up in the State out of the standing panel suggested by him earlier, to inspect the Institute, if this was not feasible a couple of officers from the N.I.C.D. could inspect the Institute and prepare the report for the State Govt. But the initiative should come from the State Government.

ORISSA

Shri R. B. Pany, Drugs Controller, Orissa stated that the Drug Control Department in the State is a part of Directorate of Medical Education and Training. He stated that Drug Control was not given due importance in matters relating to allocation of funds for strengthening it and requested that the Drug Controller (India) should visit the State and take up the matter at a higher level. He stated that there were difficulties in the distribution of drugs for want of qualified persons in the State. He sought the assistance

of the Zonal Officer in the formation of the Panel for inspecting institutions manufacturing Sera and Vaccines in the State. The Chairman agreed to this assistance being provided to the State by the Deputy Drugs Controller (India), East Zone, Calcutta.

RAJASTHAN

Shri Ashwani Kumar, Asstt. Drugs Controller Rajasthan stated that the State of Rajasthan made a very late start in Drugs Control. But within a short period they had achieved many things. There were 20 Drugs Inspectors working in the department. An Intelligence Wing had been set up and a mobile van had also been sanctioned by the State Government. A secret fund had been sanctioned for tracking down unsocial elements manufacturing and dealing in spurious drugs.

A State Drugs Advisory Board had been set up which held its first meeting under the Chairmanship of the Minister for Health recently. The intention was to create awareness of Drugs Control in higher circle.

He stated that chapter IV A of the Drugs and Cosmetics Act relating to Ayurvedic (including Siddha) and Unani drugs was being enforced in the State. He desired that there should be some training centre for Ayurvedic Drug Inspectors. He also desired that there should be some Panel of Inspection for Government Analysts Laboratories so as to improve their working. He stated that in rural area in Rajasthan there was dearth of chemists shops with the result that medicines were not available. He felt that most of the problems that were generated in the State emanated from unqualified Medical Practitioners who stock and sell drugs without giving bills. He pointed out that there was a lacuna in the State laws, as under these, it was not necessary for the Medical Practitioners to be registered. In the end he thanked the Central Drugs Standard Control Organisation in helping solve their initial problems.

MIZORAM

Dr. D. D. Arora, Drugs Controller, Mizoram stated that in their State there was no manufacturer of drugs only licences for selling drugs were issued. Recently they had appointed two Drugs Inspectors who were receiving training in Nagpur. Dr. Arora added that they did not face any serious problems.

MAHARASHTRA

Shri N. C. Venktachalam, Commissioner, Food and Drugs Administration, Maharashtra stated that he had no serious problems so far as his administration was concerned. His administration was mainly interested in the detection of spurious drugs and racketeers who indulged in this activity. He said, at present, the Drug Control Laboratory in Maharashtra was in a rented building which did not permit of any scope for expansion. They had submitted proposals to State Government to run the laboratory in a separate building. The State Govt. had allotted a piece of land for the construction of the laboratory. At present the laboratory could test about 3000 to 4000 samples annually.

Referring to the anticipated growth of the Drug Industry as mentioned by the Chairman in his opening remarks, he said that the construction of the Analytical Laboratory had to be expedited to cope with the increased load of testing.

UTTAR PRADESH

Dr. S. P. Gupta, Director of Ayurveda and Unani stated that a Drug Section was created recently in the Directorate for dealing with Ayurvedic drugs and a post of Asstt. Drugs Controller was likely to be created soon to look after this section. A panel has been appointed to screen the applications for manufacture of Ayurvedic drugs. So far 1085 applications were received and 183 applications were cleared by this panel for grant of licences. He stated tht there was no testing laboratory for Ayurvedic medicines in the State and samples were being sent to the Central Govt. Ayurvedic Testing Laboratory at Ghaziabad. He stated that no guide lines have been laid down as regards the premises for manufacture of Ayurvedic drugs. He requested the Chairman to make separate allocations of sugar and opium required for manufacture of Ayurvedic medicines instead of making combined allocations for the manufacture of both allopathic & Ayurvedic drugs as at present. He also said that musk was an important ingredient of Ayurvedic drugs and its import should be arranged by a Central Agency. He also stated that there was misuse in the state of Mritsanzeevani Sura which contained alcohol.

Replying to Dr. Gupta the Chairman clarified that there were no standards available for Ayurvedic preparations and unless Ayurvedic Pharmacopoeia was ready, testing of Ayurvedic preparations like Bhasma etc. was not possible. He further said that as far as allopathic medicines were concerned, Schedule M gave the proper guide lines for premises and equipment but in the case of premises for manufacture of Ayurvedic medicines only the general requirements have been laid down. He agreed to consider the question of separate allocation of levy sugar and opium, if the requirement of the state in respect of these for manufacture of Ayurvedic and Unani medicines were sent to him. Further, it was clarified that import of musk under the current Import Policy was permitted freely as it was covered by O.G.L. About misuse of preparations which contained alcohol, the Chairman said that State Prohibition Authorities could be asked to tackle this problem.

GOA

Dr. Frias, Drugs Controller, Goa mentioned the set up of Drugs Control in Goa and stated that it was being strengthened gradually. Govt. had already sanctioned 3 more posts of Drugs Inspectors. He complained that irrational formulations manufactured in other States were coming into Goa and said this required to be checked. He stated that they did not have laboratory facilities of their own and were utilizing the facilities of Central Indian Pharmacopoeia Laboratory, Ghaziabad. But recently Director, Central Indian Pharmacopoeia Laboratory had fixed a quota limiting samples to be tested at the laboratory and this had handicapped their plan for testing a larger number of samples. He desired that this quota should be increased. He stated that Central Assistance offered to the Laboratory in Goa could not be utilized for reasons of too much red tapism. He felt

concerned over the increasing incidence in the misuse of Psychotropic drugs in Goa and want that Schedule V for regulating such drugs should be incorporated in the Drugs & Cosmetics Rules quickly. He also pointed out that pharmacists from Goa College go outside the State for getting experience in testing of drugs and there was a dearth of experienced staff for the laboratories. He therefore desired that the requirement regarding experience in respect of Analysts should be relaxed. He mentioned that there were no standards for certain cosmetics and they were not testing these and desired to know the position in this regard. He said that there was a shortage of Streptomycin in the State some time ago but now there was a shortage of Dapsone and Insulin. He stated that chemists in his State wanted a service charge for night sale and dispensing services.

The Chairman stated that both Central Drugs Laboratory, Calcutta and Central Indian Pharmacopoeia Laboratory, Ghaziabad were experiencing difficulties in coping up with the testing of the heavy load of samples received from States. The Drugs Control authorities should use discretion in sampling of drugs for test and give preference to the testing of essential and life saving drugs. The question of getting the samples tested by the testing laboratories under the State Govts. could also be explored. He stated that the suggestion for relaxing the experience of the 'qualified person' was already being considered. Regarding cosmetics the I.S.I. are drawing up the standards for various items of cosmetics and a Group of Analysts of which the Director, Central Indian Pharmacopoeia Laboratory is member is also working out the standards. He explained that Streptomycin had been in short supply in the country owing to inadequate indigenous production of the drug and its non-availability in the international market. The shortage was temporary, and Hindustan Antibiotics had since overcome it. Speaking on the subject of shortage of Dapsone, the Chairman stated that the Hon'ble Minister of State for Health also expressed his concern over non-availability of this drug in the country and wanted chemists and druggists in States to stock this drug. Chairman further explained that chemists did not stock this drug for various reasons. Firstly it was a slow moving drug and did not offer much profit. Secondly, because the drug manufactured by Burrough Wellcome was cheaper, everybody ran after their product with the result that, that was not available. In fact Bengal Chemicals complained that their stock are not being lifted. He asked the Drug Control authorities to prevail upon a few chemists and druggists in all cities to stock this drug because this was a service item.

Answering an enquiry from Shri Sen Gupta the Chairman told the committee that the requirement of the country for Dapsone was about 18 tonnes per annum and 18 tonnes was being manufactured in the country. Shri Sen Gupta informed the committee that besides B. Wellcome and Bengal Chemicals there was a small firm in Kalyani who was manufacturing Dapsone. Shri Narsimhan mentioned that manufacturers were not coming forward to produce and market this drug because they feared that they might not get a fair price. The Chairman clarified that it was not a question of price but of technology and M/s Bengal Chemicals have in fact been allowed a higher price than M/s. B. Wellcome.

The Chairman also informed Dr. Costa Frias that recently while forwarding our comments on the Draft Drugs and Intermediate Price Control Order, the question of

providing a service charge to chemists who dispense drugs during night hours had been taken up again with the Ministry of Chemicals & Fertilizers.

ANDHRA PRADESH

Dr. Narasinhulu, Director of Indian Medicines and Homeopathy, Andhra Pradesh mentioned about the set up in the Ayurvedic Directorate of the State. He stated that rules regarding Ayurvedic medicines were being enforced in the State and requested that all communications sent to the States by the Drugs Controller (India) should also be sent to him, as he was not receiving these circulars. He stated that Ayurvedic Injections were being licensed in the State and would comply with all the tests applied to allopathic injections. He suggested that some additional popular text books on Ayurveda should be included in the First Schedule to Drugs & Cosmetics Act. He wanted assistance to procure raw materials for producing Kasturi.

Dr. Narasinhulu stated that the State Ayurvedic Board did not have the authority to curb objectionable advertisements by medical practitioners.

Shri Narasimhan informed the Committee that in Tamil Nadu, rules have been framed under a code of ethics whereby Ayurvedic medical practitioners were not allowed to advertise themselves.

Shri M. V. Thomasa, Drugs Controller, Andhra Pradesh stated that in his state Food & Drugs Control has been from the Directorate of Medical Health Services so that proper attention could be paid to their control by a whole time officer. He stated there were three districts in the State without Drug Inspectors and he hoped to have one Inspector for each district. He said that a combined Food & Drugs Laboratory was being built in Andhra Pradesh with Central assistance but the lack of cement came in the way of constructing it. They had appointed a separate Govt. Analyst for drugs in their laboratory. He informed the Committee that a Drug Advisory Committee had been set up in the State. He stated that drugs were procured for the State against Rate Contract only from firms which were in the market for 5 years. He stated that the dearth of pharmacists was agitating the entire business community in the State.

The items on the Agenda were then taken up for consideration.

Item No. 1 : Confirmation of the minutes of the last meeting of the Drugs Consultative Committee.

The minutes were confirmed.

Item No. 2 : Action taken on the recommendations made by the Drugs Consultative Committee at its last meeting.

Annexure – I to the Agenda :

(a) Item No. 33 : Qualification of Analytical Chemist.

The Chairman explained that the comments received from the Drugs Control authorities on the subject indicated that there was near unanimity in regard to the academic qualifications proposed for an Analytical Chemist to be in charge of testing in a manufacturing establishment but there was divergence of views on the quantum of experience. After much discussion the committee agreed that the Analytical chemist should have adequate experience in the opinion of the licensing authority, and that Rules 71 and 76 of the Drugs & Cosmetics Rules should include the following provision :-

“The Head of the testing unit shall possess a degree in Medicine, or Science or Pharmacy or Pharmaceutical Chemistry of a University recognized for this purpose or hold an Associateship Diploma of the Institution of Chemists (India) obtained by passing the said examination with ‘Analysis of drugs and pharmaceuticals’ as one of the subjects, and shall have experience in the testing of drugs, which in the opinion of the licensing authority is considered adequate.”

(b) Item No. 34 : Preparation of Standard Plans, Blue Prints and guidelines for drug manufacturing units.

The Chairman explained that although a sub-committee was constituted for the purpose at the last meeting, it could not meet for various reasons and now most of the members of this sub-committee are not with the various Administrations. The sub-committee, he recalled was appointed to draw up standard building plans for manufacture of different categories of drugs, including the laboratory facilities showing the layout, design, minimum area, provision for the type of equipment, their cost, the source of supply, the placement of equipment, service lines etc. on the lines of a project report. He said that in case a report on these lines could be prepared, it could be very helpful to the State Drug Control authorities and they could act more actively in licensing prospective entrepreneurs.

It was agreed that the sub-committee should be reconstituted as under and should present its report within a period of one year and preferably before the next meeting of the Drugs Consultative Committee for its consideration :-

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| 1. The Drugs Controller,
Karnataka State,
Bangalore. | Chairman |
| 2. Director of Drugs Control,
West Bengal, Calcutta. | Member |

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| 3. Director, Drugs Control Administration,
Gujarat State, Ahmedabad. | Member |
| 4. Drugs Controller, Goa,
Panaji. | Member |
| 5. Joint Commissioner,
Food & Drugs Administration,
Maharashtra State, Bombay | Member |
| 6. Deputy Drugs Controller,
Delhi Administration, Delhi. | Member |
| 7. Deputy Drug Controller (India)
South Zone, Madras. | Member-Secretary |

(c) Item No. 36 : Packing of Drugs meant for paediatric use.

The Drugs Controller, Rajasthan desired that some time limit should be fixed by which the decision of the committee that drugs meant for paediatric use should be allowed to be marketed only in consumer packing and not in bulk packing, should be enforced by all States. The Committee decided that this decision should be enforced by September, 1978.

**Questions arising out of the minutes of the last meeting
of the Drugs Consultative Committee.**

Item No. 3(a) : Consideration of the question of permitting the manufacture of "Dental Tooth Paste" and "Dental Tooth Powder" containing 50% tobacco powder.

The Chairman explained that the opinion given by the Tata Memorial Centre, Bombay and the Gujarat Cancer Research Institute was that the use of Dental Tooth Past and Dental Tooth Powder containing tobacco exposed the people to the risk of cancer and was definitely hazardous to health. In an extensive study conducted by the Cancer Institute, Cuttack, it was also revealed that constant use of tobacco produced cancer. The Chairman invited the views of the members as to whether in the light of these findings manufacture of Dental Tooth Paste and Tooth Powder containing tobacco could be permitted.

The Drugs Controller, Orissa said that in Orissa a large number of items like Gudakhu were being manufactured and utilized by more than 5 crores of people daily and even after they were brought under control as

'Cosmetic', there would be difficulty in stopping them. But at the same time he wanted that their use should be checked as they are carcinogenic.

The Commissioner, Food & Drugs Administration, Maharashtra stated that they allowed Tobacco Tooth Paste as a cosmetic provided it did not contain more than 10 % in the form of burnt tobacco.

The Drugs Controller, Madhya Pradesh informed the Committee that about 100 concerns were manufacturing items containing tobacco in Madhya Pradesh.

The Drugs Controller, Punjab said that people in his State regularly used Zarda containing 80% tobacco and it was a problem to control the use of Zarda.

The Director of Drugs Control, West Bengal stated that there was a judgment from Orissa High Court after which manufacturers were directed to obtain a cosmetic licence for pastes and powders containing tobacco.

The Drugs Controller, Delhi observed that as in the case of cigarettes, a warning should be required to be displayed that 'Tobacco chewing is a Health Hazard.'

The Chairman said that banning the use of tobacco in dental preparations is a difficult proposition. Either a limit can be placed on the tobacco content of these pastes and powders as in the State of Maharashtra or its use should be discouraged.

The Director, Central Indian Pharmacopoeia Laboratory stated that from the analytical angle it would be difficult to indicate the percentage of tobacco present in a particular paste or powder.

Considering the various view points, the committee decided that manufacturers should be told that use of both pastes or powders containing tobacco is fraught with the risk of cancer and dissuaded from marketing such products. In the case of Orissa, the Chairman agreed to a communication being sent by the D.G.H.S. to the Director of Medical Education and Training to discourage the use of Gudakhu in Orissa. Copies of this letter would be endorsed to the Director of Medical and Health Services in other States and also to the members of the committee.

Item No. 3(b): Permission for use of polythene containers for packing of oral liquid preparations.

The Chairman stated that the Drugs Consultative Committee had earlier taken a decision that polythene containers should not be used for packing

of liquid oral preparations. Since then I.S.I. have published standards for polythene containers. A report from W.H.O. also said that normally it may not be harmful to use polythene containers for liquid oral preparation. This would of course depend upon the composition of the preparations. In Maharashtra and in Gujarat polythene containers were allowed to be used. This provoked certain manufacturers in other States also to use polythene containers for their liquid oral preparations.

The Chairman stated that the I.S.I. standards could be adopted and the manufacturers asked to produce data on compatibility and stability studies before permitting any particular product to be packed in polythene containers. There is, however, no question of permitting the use of PVC containers which are definitely harmful. A view has to be taken in the matter so that the practice adopted in all the States in the country is uniform.

It was pointed out by some members that even milk was being marketed in polythene containers but it was observed that milk got spoiled within 24 hours. Again polythene containers are ill suited for packing of preparations containing chloroform, iodine tinctures etc.

The Drugs Controller, Mizoram pointed out that cough mixture concentrates for Influenza etc. were being supplied in bulk polythene containers throughout the Eastern Region and its is necessary to ensure that the quality did not get affected because of the packing. If necessary, items which should not be packed in polythene containers must be specified.

The Chairman suggested that a small committee should be constituted to go into the question of use plastic containers for packing of oral liquid preparations and to recommend the conditions under which plastic containers should be allowed to be used. The Committee agreed to the proposal and set up a sub-committee consisting of the following members for the purpose :-

- | | |
|---|------------------|
| 1. Joint Commissioner, (Shri V.D.Deshmukh)
Food & Drug Administration,
Maharashtra. | Chairman |
| 2. Drugs Controller, Goa. | Member |
| 3. Joint Drugs Controller,
Tamil Nadu. | Member |
| 4. Dy. Drugs Controller (India)
West Zone, Bombay. | Member-Secretary |

It was further decided that the findings of the sub-committee should be furnished within a period of three months till then status quo should be maintained in the matter.

Item No. 4 : Suggestion from Dr. Rajendra Prasad Centre for Ophthalmic Sciences that suitable dispensing containers for exclusively eye preparations may be prescribed.

The Committee considered the question of use of distinctly coloured bottles for eye preparations or of displaying the figure of an eye on the labels of such preparations but felt that not much purpose will be achieved by such action since it appeared to be more a dispensing problem than a manufacturing problem. Further there are certain eye preparations which are also intended for the treatment of disorders of the ear. The case referred to by the Centre also appeared to be a solitary one and the committee did not agree to its proposal that suitable dispensing containers exclusively for eye preparation may be prescribed.

Item No. 5 : Proposal for labeling of particulars of drugs in Hindi.

The Chairman said that suggestions have been made by certain Members of Parliament and also by the consultative committee of Parliament that the particulars of drugs which were given at present on the label of the container of drugs only in English should also be shown in Hindi.

The Committee was of the view that drugs have been moving inter-State commerce and there are certain regions of the country where Hindi is not spoken and understood at all, particularly in Southern State and North Eastern States. It was also felt that in view of a number of particulars having to be furnished on the labels under the Rules, there will not be adequate space on the labels to display them both in English and Hindi. The Chairman stated that since Hindi is our National language, it could be considered as to whether certain particulars such as name of the drug and cautionary legends intended for the guidance of the patient e.g. 'Poison' etc. could be given both in English & Hindi. A view was expressed that in that case each State may insist on such labeling in the regional languages. After considerable discussion, the Committee came to the conclusion that although labeling with a few particulars also in Hindi might be all right in principle, it might present difficulties particularly in the non-Hindi speaking states, where most of the people and the medical profession have no knowledge of Hindi. It is also a sensitive matter on which State Governments have strong views. It was therefore decided that Government of India should ascertain the views of the State Governments in the matter.

Item No. 6 : Proposal that advertisements relating to Drugs intended for treatment / cure of Asthma should be regulated under the provisions of the Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954.

The Committee unanimously agreed to the proposal and recommended that the disease 'Asthma' should be included in the Schedule to the Act.

Item No. 7 : Consideration of the measures to curb the reported hiring of licences / registration certificates by unscrupulous pharmacists.

The Chairman explained that there was a news item in the 'Indian Express' to the effect that in certain States unscrupulous pharmacist loan their name to various unscrupulous Drug Store Owners at a time and it was difficult to find out whether the same qualified person was working in more than one shop. The President Pharmacy Council of India had suggested that if the State Drug Control authorities maintained a list of approved qualified persons alphabetically together with their placement it would help considerably to check this malpractices.

Shri Pany, Drugs Controller, Orissa stated that in their State a list of qualified persons is maintained and an undertaking was taken from every pharmacist to the effect that he has not been engaged elsewhere.

It was pointed out that shortage of qualified persons is one of the causes leading to this malpractice. The Drugs Controller, Madhya Pradesh said that the list as proposal by the Pharmacy Council of India will not completely eliminate this practice but it will certainly reduce it. The Drugs Controller, Andhra Pradesh supported the proposal of a list being prepared.

After discussion, the Chairman agreed with the committee that it was a step in the right direction and to start with, every Drug Controller should prepare a list of qualified persons / registered pharmacists of all the selling establishments in the State region-wise. This list should serve as a check list while issuing or renewing licences to all chemists / pharmacies.

Item No. 8 : Proposal for the ban on the use of chloroform as an ingredient of human drug and cosmetic products.

The Chairman explained that it has been found that chloroform can produce cancer in experimental mice and in U.S.A. the use of chloroform in drug, cosmetic and food products has consequently been banned. The opinion sought from the I.C.M.R. indicates that in India chloroform is used in extremely small amounts and exposure to patients to chloroform is very little and it does not appear to be hazardous to human health. The Chitranjan National Cancer Research Centre has suggested that Govt.

should wait for more details and may ask the Industry in the meantime to reduce the use of chloroform by 50%. The Chairman mentioned that recently he had received an extract from the Pharmaceutical Journal published in U.K. It is seen from the extract that in U.K. the use of chloroform is limited mainly as a preservative and total ban on its use has not been imposed there. (Ref.PJ.Vol.220, No.5971 of 20th May, 1978).

There was some discussion after which the Committee agreed to follow the practice in U.K. It was decided that a directive should be issued from the Drugs Controller (India) to all the States that manufacturers should be advised to reduce the content of chloroform in their formulations so as not to exceed 0.4%. It was also agreed that this measure should be enforced as early as possible but in any case not later than 1st January, 1979.

Item No. 9 : Certification scheme on quality control of pharmaceutical products moving in International Commerce.

The Chairman explained to the members the salient features of the W.H.O. Certification Scheme. He stated that India has agreed to participate in the scheme. The members were told that under the certification scheme Drugs Controller of various States from which exports of drugs are likely to be made have been designated as 'Competent Authority' for issuing certificates about the manufacturers of drugs in their States when approached by the importing country. He also stated that manufacturers of drugs have been designated as 'competent authority' for issuing 'batch certificates' in respect of individual batches of products which are manufactured by them for export purposes. He, therefore, emphasized the need for a thorough inspection of such firms so as to ensure that they observe the necessary controls on quality during and after manufacture and follow Good Manufacturing Practices before a certificate is issued in their favour. He also suggested that a separate list of all such firms be maintained who could be relied upon for supplying quality drugs and a copy of the list may also be furnished to him. A Joint Inspection of these firms should also be carried out periodically. The intention is that country's fair name should not be tarnished in the eyes of the importing countries.

After considering the aspects mentioned by the Chairman, the committee agreed that the under mentioned guidelines should be followed :-

1. Joint Inspection of manufacturing firms by senior officers of the State Drugs Control Organisation and Zonal offices should also be carried out before issuing certificates in their favour under the WHO Certification Scheme.

2. It should be ensured that the firm is observing Good Manufacturing Practices and have checks on controls exercised.
3. The certificate should be issued only after the importing country approaches the 'Competent Authority.'
4. 'Batch Certificates' are to be issued only by the firms concerned.
5. A list of firms in favour of which the competent authority i.e. the State Drugs Controller concerned has decided to issue certificates under the scheme should be prepared by him a copy also furnished to the Drugs Controller, India.

Item No. 10 : Proposal for charging extra fee for granting drug licences to the firms where a change in the constitution of the firm takes place but the same has not been intimated to the licensing authority within the prescribed period.

The Chairman agreed to examine the problem in consultation with the Ministry of Law and requested the Director, Drugs Control Administration, Gujarat and the Joint Commissioner, Food and Drugs Administration, Maharashtra to send him a note on the issues involved and the difficulties faced by them in their respective States in the matter.

Item No. 11 : Labelling of contents of oral liquid – rule 96(1)(iii) (a) – Proposal for amendment.

The Committee decided that rule 96(1)(iii)(a) be amended at an appropriate time as suggested by PAMDAL and till then manufacturers may be permitted to express the composition of the product per dose in the case of preparations having a dose of less than 1 ml as in case of paediatric drops.

Item No.12 : Difficulties represented by Small Scale Units in setting up separate laboratories for testing drugs – request that relevant amendments to Rule 71, 71-A and 76 of Drugs and Cosmetics Rules may not be enforced in this regard.

The Chairman explained that the Drugs and Cosmetics Rules were amended recently requiring every manufacturer of a drug whether big or small to have his own drug testing laboratory. This measure was taken to improve the image of the manufacturers particularly those in the Small Scale Sector. After the publication of this amendment, representations from Associations of Manufacturers and individual manufacturers have been received by Government against this amendment. There was also a Parliament question on this. The points in the representations are :

- i. Small Scale Units will find it financially very difficult to set up such a laboratory.
- ii. They will find it very difficult to get fully qualified persons and
- iii. The person if appointed will not be fully utilized.

He invited the views of the members as they will have to implement this in their respective States.

The Drugs Controller, Punjab and the Joint Drugs Controller, Tamil Nadu were of the view that in initial stages people with small investment would find it difficult to build their own testing laboratories. It may also affect repackers in the State of Tamil Nadu, causing unemployment.

The Director, Drugs Control Administration, Gujarat State, Commissioner, Food & Drug Administration, Maharashtra, Director, Drugs Control, West Bengal, Commissioner, Food & Drugs, Pondicherry, Drugs Controller, Andhra Pradesh and Drugs Controller, Delhi were strongly in favour of the amendment. In support of the decision the following points were made :-

1. The cost of laboratory is only 0.5 to 1% of the total turnover, taking the really small scale industry in the field of drugs.
2. Certain minimum norms have to be laid down. There has been no perspective planning in this direction otherwise we could have had these laboratories long back. As a short term measure the manufacturers were allowed the facility of approved laboratories. The position that manufacturers should not have these laboratories particularly when the production of the industry is expected to increase substantially, would be suicidal. Manufacturers should be insisted on to have their own separate laboratories.
3. Already there has been some criticism in the public that there has been mushroom growth in the Drug Industry. The need for gaining the public confidence makes it all the more important that each manufacturer should have his own laboratory.
4. Where, for testing of a drug a sophisticated equipment is needed, then the drug could be allowed to be got tested from outside in an approved laboratory where such facilities are available. But routine testing of raw materials and finished products should be done in manufacturers' own laboratory.

5. Where items like surgical dressings, Disinfectants-Phenyl, Clove oil etc. (which require only limited number of tests to be carried out) are manufactured by small manufacturer having adjacent or common premises, they can pool their resources to have a common laboratory on a co-operative basis.

The Drugs Controller, Goa then suggested that for implementation of these Rules some time lag needs to be provided.

The consensus of opinion of the committee was that new units should not be licensed unless they establish their own testing laboratory. It should be made clear to the manufacturers who have already been licensed and getting their products tested from an approved laboratory, that they will have to establish their own laboratory and sooner they build one, it will be better for them. In any case grant of permission for availing the testing facilities of an approved laboratory should be restricted only to units already licensed and this concession should not be made available later than 1st January, 1980. No objection should be taken in the case of co-operative laboratories in the case of 2 or 3 firms located in the same area and manufacturing similar products. But this decision too should be exercised as an exception rather than as a general rule.

Item No. 13 : Consideration of the question relating to the fixation of a specific date for the stoppage of the manufacture of a combination of Analgesics, Antipyretics and Cortico-steroids formulation.

The Chairman explained the genesis of the recommendation of the Essential Drugs Committee that fixed combinations of Analgesics, Antipyretics and Corticosteroids should be stopped from being marketed. The treatment of a patient should start with simple remedies e.g. Aspirin. However, if the doctor feels the necessity of the drugs e.g. Analgin and prednisolone he can prescribe them to be taken separately. But when combinations of such preparations are marketed, the patient may get a quick relief but in the long run he has to pay the price in the form of side reactions. The experience in other countries is the same. Even WHO have recommended against the manufacture of these fixed combinations. The Chairman pointed out that some States are implementing the decision but some States wanted that a date should be fixed for the manufacture of these combinations to be stopped.

The Committee, after some discussion agreed that manufacture of fixed combinations involving Analgesics, Anti-pyretics and Cortico-steroids should be stopped with effect from 1st January, 1979 and after that date no manufacturer in any State should be allowed to manufacture these formulations.

Item No. 14 : Consideration of the question relating to the fixation of a specific date for the stoppage of the manufacture of formulations containing Halogenated Hydroxyquinolines.

The Chairman explained that I.C.M.R. has recommended that of a large number of drug formulations that are available in the market and which contain halogenated Hydroxyquinolines, a few only have adequate therapeutic justification. While en tero vioform can be used for dysentery, Enzyme preparations or antiflutulence preparations containing derivatives of halogenated hydroxyquinolines should not be allowed to be used. This requires screening on the part of State Drugs Control departments so as to allow only such preparations to be manufactured and marketed as have scientific basis and are pharmacologically and therapeutically of value. Permission already granted should also be withdrawn if there is no therapeutic rationale for any combination. While these combinations should be screened at the State level, in cases of doubt, the Central Drugs Control Organisation can assist by having them examined from experts.

The Committee then decided that manufacture of irrational formulations containing Halogenated Hydroxyquinolines should be stopped with effect from 1.1.79.

Item No. 15 : Risk of cancer due to the use of some Hair Dyes.

The Committee was of the view that as the dye in question namely "2.4 diamino-anisole", is not used to any appreciable extent in India, no action need be taken to ban its use in cosmetics.

Item No. 16 : Standards for disinfectant fluids as given in Schedule O or ISI standard applicability of.

Item No. 17 : Status of drugs deleted from the official references.

As the Drugs Controller, Karnataka who had suggested these item was not present, these items were not discussed.

Item No. 18 : Procedure of licensing authority in case of rejection of application to manufacture for sale drugs and cosmetics.

The Committee agreed that a uniform procedure should be provided in the Drugs and Cosmetics Rules as a guideline to be followed by the licensing authority in the case of rejection of applications for manufacture for sale of drugs other than those specified in Schedule C & C(1) as well as Cosmetics as has been specified in the case of Schedule C & C(1) drugs.

Item No. 19 : Additional Test for Whole Human Blood.

The Director, Drugs Control, West Bengal stated that it is necessary to provide a test for Infective Hepatitis for whole human blood in the Drugs and Cosmetics Rules and some cases of Infective Hepatitis on transfusion of Blood have come to light.

The Chairman said that it is to be ensured first that the testing kit for Australian Antigen Test is available. He agreed that so far as safety of blood is concerned, blood banks should be asked to carry out the Australian Antigen Test. This will eliminate the risk of getting jaundice after blood transfusion. He further suggested that Test Kits can be imported for this purpose.

Shri Shastri, Director, Drugs Control Administration, Gujarat quoted for the benefit of the members that W.H.O. Technical Report Series No.512 and 570 give the details of the test.

The Joint Drugs Controller, Tamil Nadu suggested that Rule 76(1) and (2) and (3) should be amended so as to cover (part XII B) of Schedule F so that Blood Banks can be licensed. The Committee agreed to the proposal.

Item No. 20 : Dearth of Registered Pharmacists.

The Chairman pointed out that this subject had been raised by many States and the problem was rather difficult. He explained that in 1970 the Drugs and Cosmetics Rules were amended requiring that only a Registered Pharmacist should supervise the dispensing and sale of Schedule E. H & L drugs in chemists shops. Many of the States have represented that due to dearth of pharmacists they are finding it difficult in rural areas and semi urban areas to implement this provision. Partly this problem is due to the fact that Diploma holders in pharmacy who are an educated class do not want to shift to rural areas. There is another dimension to this problem. With the coming into force of Section 42 of the Pharmacy Act from September, 1981 only Registered Pharmacist could be permitted to dispense drugs. If recognition is given to persons again as 'Qualified Persons' on the basis of experience only by opening up the provisions of Rule 65(15)(c). Such persons will not have locus standi on the specified dated unless the Pharmacy. Act is amended again. The Chairman stated that this problem was discussed in the Central Council of Health and with reference to the resolution passed by the C.C.H., the Government of India, Ministry of Health and Family Welfare have written to all State Governments inviting their views on the subject. The Chairman expressed his apprehension that if persons are brought into the profession merely on the basis of experience there was the possibility of

person with no qualifications whatever entering into it and persons with the required qualifications in pharmacy being out of job.

The Director, Drugs Control, West Bengal and the Drugs Controller, Uttar Pradesh were of the view that dispensing of Schedule H & L drugs and operation of pharmacy should be separated and where compounding of drugs on doctor's prescription is needed, employment of a Registered Pharmacist should be insisted upon but otherwise there is no necessity of a Registered Pharmacist.

The Drugs Controller, Gujarat suggested that training could be given to those who hold registrable qualifications but were not registered. Rule 65(15)(c) should also be amended so as to recognize persons with experience as on 31st Dec., 1980 as 'Qualified Persons'.

The Drugs Controller, Punjab supported this view. He said that in Punjab medical services were spreading very fast and at the same time there was difficulty in procuring drugs. All the medicines were not available in the Hospitals and quite a lot of them have to be purchased from the market. It will be difficult for the people to procure these drugs unless 'Dispensing preparing mixtures etc.' is separated from the sale of drugs at the counter. He suggested that since we needed a large number of qualified persons for the purpose of enforcement of the Drugs & Cosmetics Act, a short-term course of a duration of six months for imparting training to Matriculates in Sciences may be started in Govt. institutions. These persons should be permitted only to sell drugs over the counter but not to compound drugs.

The Dy. Drugs Controller, Delhi Administration informed the Committee that Pharmacists in Delhi have become very expensive. The Executive Councillor had accordingly written to the Health Minister that those chemists who are matriculates with Science and have some experience of dealing with drug may be allowed in place of a registered pharmacist.

The Drugs Controller, Andhra Pradesh endorsed the views of the Drugs Controller, Punjab. He said that it will not be practical to implement the decision of the Pharmacy Council of India as diploma holders in Pharmacy are not available for all practical purposes and it is difficult especially in villages to employ a Registered Pharmacist.

The Drugs Controller, Goa stated that some states trained an adequate number of Pharmacists but some did not. On this account the more progressive states should not be pulled back.

The Commissioner, Food & Drugs Administration, Maharashtra was of the opinion that if prior to the amendment of Rule 65(15)(c) in regard to

the 'qualified person' the system was working satisfactorily, it would be available to revive the old provision.

The Chairman said that the object of the amendment was to ensure that the profession of Pharmacy was practiced by only the professionalists.

The Drugs Controller, Orissa pointed out the differences from State to State in the closing of the First Register. He desired that those who are in the drug trade as on 1/1/1979 should be given a training of 3 months and then recognized.

The Joint Drugs Controller, Tamil Nadu said that there was no shortage of qualified persons in Tamil Nadu. They were producing 275 pharmacists every year but had reduced that number now. He however, expressed concern over the suggestion of some members who were proposing to create a class of sub-standard pharmacists. He said that the problem in villages was that there were no medical practitioners. It was therefore not economical to run a 'Pharmacy in the villages.' The minimum needs of the villages could, however, be met by dealers holding restricted licences. He also informed the Committee that the Pharmacy Council of India had appointed a sub-committee which has prepared a list of drugs which could be sold without the agency of a pharmacist. The role of pharmacists should not be ignored. The practitioner and the pharmacist maintain a double check before the medicine is used by the patients.

The Drugs Controller, Madhya Pradesh suggested that it would be helpful if the qualifications were relaxed and persons having adequate experience are allowed to be registered.

The Director, Drugs Control Administration, Gujarat was of the opinion that unless Government gave some sort of incentive to run a pharmacy in rural areas and unless the pharmacists are sure of having a sale of Rs.600/- per day, nobody would be willing to invest.

The subject was discussed at length in regard to the nature of relaxations that have to be made in the existing rules so as to overcome the shortage of qualified pharmacists and as to whether such relaxations should be in respect of cities and / or rural areas or should be based on the population of the area concerned. After considerable discussion the Committee took the following decisions :-

- (1) For operation of a 'pharmacy' the employment of the services of a Registered Pharmacist as defined in the Pharmacy Act should be insisted upon.
- (2) For places having a population of less than 20,000 persons, a person who has passed the matriculation examination with science

or any other equivalent examination and who has also passed a short term training course of a duration of 6 months approved by the State Govt. may be recognized as a 'Qualified Person.'

Item No. 21 : Patents and Proprietary Homeopathic medicines.

This item came for discussion when Dr. Jugal Kishore, Hony. Adviser to the Govt. of India, Ministry of Health & F. W. was present. A question was raised whether patent and proprietary Homeopathic medicines, which are combinations of drugs can be licensed.

Adviser, Homeopathy clarified that the definition of Homoeopathic medicines as given in the Drugs and Cosmetics Rules covers combinations of Homoeopathic medicines. Although some Puritans do not use combinations but only single drugs, those who are pragmatic use combinations for instance, Biochemics are combinations. One or other of the remedies included in the combination works.

The Chairman stated that those combinations of Homoeopathic drugs which are already in the market could continue but as far as new combinations are concerned, it would be necessary to seek the advice of the Adviser, Homoeopathy and such cases may be referred to this Directorate. Adviser, Homoeopathy stated that there should be some basis for proposing a new combination product. For this, some clinical data with regard to the new combinations when used at least in not less than 20 cases should be made available. The new combination should be proved clinically beneficial. On the basis of experience with previous combinations and the clinical data submitted it should not be difficult to judge whether a certain new combination of Homoeopathic medicines can be allowed to be marketed or not. The Adviser, Homoeopathy stated that he will furnish the guidelines in regard to the data to be submitted for clearance of new Homoeopathic combinations.

In reply to another question as to how the quality of a homoeopathic drug can be determined, the Chairman clarified that for this purpose the Homoeopathic Doctors in the State who are using the drug could be consulted. If the opinion given is against its effectiveness, the supplier concerned, should not be considered for procurement of the item.

The Adviser, Homoeopathy stated that facilities have been established for testing Mother Tinctures and triturates of low potencies. The Chairman thanked the Adviser, Homoeopathy for his attending the meeting and giving the Committee the benefit of his valuable advice.

Item No. 22 : Modern Potent and New Drugs.

The Joint Drugs Controller, Tamil Nadu wanted to know how far the State Drugs Control authorities should be responsible to ensure compliance of the various conditions imposed by the Drugs Controller (India) while approving modern potent and new drugs.

The Chairman explained that the object of imposing various restrictions / conditions with new drugs is to protect the consumer and ensure that they are used indiscriminately. For instance they are required to be used under the direct supervision of a specialist in a T.B. Hospital or a Cancer Institute etc. This would besides ensuring that these drugs which are highly potent are used with caution or as a second line of treatment help in keeping a track on the adverse reactions of a drug which did not manifest themselves during the earlier stages of its use but only after its release for large scale use. The Chairman therefore requested the members to enforce the conditions relating to approval of new drugs as best as they can. If a firm is found to contravene any of the conditions of approval of a 'New Drug' the State Drugs Controllers can bring such cases to his notice.

Item No. 23 : Allotment of Levy Sugar to Pharmaceutical Industry.

The Joint Drugs Controller, Tamil Nadu wanted to know how to check that levy sugar recommended in favour of pharmaceutical manufacturers in the State is not misused.

The Chairman explained that because prices of drugs are determined on the basis of the cost of raw materials including sugar, Government of India have been issuing levy sugar to Pharmaceutical Industry, which is supplied at cheap prices. Some States have complained that instead of making use of the supply of levy sugar for the specific, purpose of manufacturing drugs, some firms dispose of the sugar in the market. The Chairman therefore stressed that some sort of checks should be exercised by the State Authorities so that the facility which have been given to pharmaceutical manufacturers is not misused. The State Drug Inspectors could when they inspect manufacturing firms make a random check regarding the proper utilization of sugar.

Item No. 24 : Insecticides.

The Joint Drugs Controller, Tamil Nadu pointed out that Central Insecticide Board is not treating certain preparations containing D.D.T., B.H.C. etc. e.g. Antilice preparations as Insecticides but direct the firms to register them under the Drugs & Cosmetics Act. AS such insecticides are not covered under Sec. 3(b)(ii) of the Drugs & Cosmetics Act as drugs, the procedure to be followed in such cases may be decided.

The Chairman clarified that a policy decision has been taken that those preparations which are used as drugs will not be registered by the Central Insecticide Board. Such preparations will be covered under the Drugs & Cosmetics Act under Section 3(b)(i) as preparations which are used for treatment of diseases like pediculosis.

Item No. 25 : Licence for Ayurvedic Medicines.

As the Drugs Controller, Bihar was not present to explain his view point, the item could not be considered by the Committee.

The Chairman, however, introduced Hakim M.A.Razzack, Deputy Adviser (Unani) from the Ministry of Health & F.W. to the Committee and suggested to the members that if they had any point on Ayurvedic they could consult him. Shri Deshmukh enquired whether combination products of modern and Ayurvedic drugs could be permitted to be manufactured.

The Chairman clarified that according to the decision already taken by this Committee such combinations should be treated as 'New Drugs' and in such cases the protocols of the methods of manufacture, the methods of tests, results of clinical trials etc. have to be called for from the manufacturers. Such cases may be referred to the Adviser, I.S.M., Ministry of Health & F.W. for his expert advice. However, preparations such as Matronidazole in combination with an Ayurvedic drug should not be permitted.

Shri Ashwani Kumar (Rajasthan) pointed out that in Rule 157 no experience in manufacture of tablets, capsules etc. was prescribed unlike in the case of allopathic drugs and therefore wanted to know whether Ayurvedic Tablets, Eye Lotions etc. should be permitted or not.

Shri Razzack said that it would depend upon whether the manufacturers have the necessary qualification, experience and competence to manufacture such products. In any case if a note containing the points is sent to him, it could be considered.

The Commissioner, Food & Drugs Administration, Maharashtra enquired whether Ayurvedic drugs could be permitted to be manufactured on Homoeopathic principles. He said that there was a proposal by a party to dilute Ayurvedic drugs and prepare tinctures etc. as in Homoeopathy. Shri Razzack clarified that this was not permissible and Ayurvedic drugs should be manufactured according to Ayurvedic principles.

Shri Ashwani Kumar desired that there should be a Scheme of Training of Drugs Inspectors in Ayurveda. Hakim Razzack said that a scheme in this

regard has been included in the Sixth Plan proposals. The Chairman added that certain States e.g. Maharashtra and Tamil Nadu have training facilities in their States and Rajasthan authorities can contact them, if necessary.

Commissioner, Food & Drugs Administration, Maharashtra wanted to know whether colours and preservatives could be allowed in Ayurvedic preparations and whether some decision has been taken in this regard.

Hakim Razzack replied to say that these aspects were coming up before the Ayurvedic Drugs Technical Advisory Board for consideration and the decision taken would be communicated to the State Drugs Controllers.

The Director of Indian Medicine, Andhra Pradesh pointed out that some of the books mentioned in the First Schedule to the Drugs & Cosmetics Act are not available and in case the manufacturers quote certain authoritative Text Book, it will be difficult for the licensing authority to check it. It was agreed that these books of reference should be made available. The Director of Indian Medicine, Andhra Pradesh and the Joint Drugs Controller, Tamil Nadu also suggested that the Ayurvedic Formulary of Andhra Pradesh and Sarabhoji's book on Ayurveda should be included in the first Schedule. The representatives from Uttar Pradesh stated that there should be a Central agency like S.T.C. to import and distribute 'musk' (Kasturi) to Ayurvedic manufacturers. Hakim Razzack said that 'musk' has been included in the open General Licence List of the Import Policy and manufacturers can directly import this item.

Shri Ashwani Kumar (Rajasthan) wanted to know about the shelf life of certain Ayurvedic preparations. Hakim Razzack said manufacturers are required to indicate the 'date of manufacture' on the label of such preparations. The Chairman pointed out that from the point of view of shelf life it is the date of expiry which is more important and suggested that in case of Ayurvedic items which are likely to deteriorate both the date of manufacture and date of expiry should be given. Hakim Razzack agreed to bring the matter before the Ayurvedic Drugs Technical Advisory Board.

The Director of Ayurveda from U.P. asked if he could be provided quota of opium and Bhang. The Chairman said that so far as bhan is concerned there is no Central distribution of this item. He, however, could write to the Drugs Controller (India) about the State's requirements of opium separately.

Shri Hakim Razzack clarified with reference to a query from the representative of Karnataka that the addition of extraneous alcohol should not be permitted in Ayurveda Proprietary medicines.

Regarding Ayurvedic Injections being made in U.P. and Andhra Pradesh, the Chairman said that these should be tested for sterility Pyrogen and Toxicity and manufacturers should also be required to ensure that the products comply with these tests before they are released for sale.

The Chairman thanked Hakim Razzack for assisting the Committee with his expert advice.

Item No. 26 : Packing of Patent and Proprietary medicines – enforcement of the provisions of Rule 105 of the Drugs & Cosmetics Rules, 1945.

The Assistant Drugs Controller, Rajasthan pointed out that the provisions of Rule 105 are not being implemented uniformly throughout the country and a large number of patent and proprietary medicines e.g. capsules, tablets etc. are being marketed in bulk packing and not in consumer packing intended for retail sale.

After some discussion, the Committee decided that 'Retail Pack' may be determined on the basis of dosage and current practice and enforced strictly. To start with, Schedule H and L drugs, and drugs which are likely to deteriorate on storage and are labeled with an expiry date should be allowed to be marketed in small packings only.

Item No. 27 : Licensing of hospitals engaged in the manufacture of Drugs & Medicines.

Shri Ashwani Kumar said that it is understood that All India Institute of Medical Sciences, New Delhi has been granted licence in Form 28. In their State also a large number of I.V.Fluids in some Hospital Pharmacies are manufactured. However, the legal position is not clear whether Hospitals can be licensed. He desired that clear and uniform guidelines should be evolved in the matter.

Commissioner, Food & Drugs Administration, Maharashtra State observed that in their State the legal departments was of the opinion that as Hospitals were engaged in the 'distribution of drugs', they could be licensed and they are therefore licensing them.

The Chairman asked Shri Ashwani Kumar to consult the legal department in his State and obtain their advice. He however, informed the Committee that the Drugs & Cosmetics Act is being amended to enable licensing of Hospital Pharmacies where drugs are being manufactured.

Item No. 28 : Recommendation made in the meeting of the Govt. Analyst and Drugs Inspectors held in Jaipur on 11th October, 1976 for consideration

- (i) The Assistant Drugs Controller, Rajasthan stated sometimes the sample of a drug is not adequate enough divide it into 3 or 4 portions but at the same time analysis of the sample is of great importance. He desired that in such cases the quantity of the sample available should be allowed to be tested from the Central Drugs Laboratory, Calcutta through a Court.

The Deputy Drugs Controller, India stated that the Court cannot take upon itself the role of the prosecutor.

The Drugs Controller, Andhra Pradesh pointed out that sending the drug through a Court will not solve the problem as it cannot be done.

The Commissioner, Food & Drugs Administration, Maharashtra expressed the view that when it is not feasible to adopt the procedure laid down in the Drugs & Cosmetics Act for testing a sample of a drug, the help of the Police can be sought and the sample of the drug seized and sent for analysis under the provisions of the Indian Panel Code.

The Joint Drugs Controller, Tamil Nadu observed that probably this measure cannot be resorted to as the law is not silent on the procedure of sending the sample for test.

The Chairman concluded that as the law stands today there is no provision for adopting a procedure different from what is laid down in the Drugs & Cosmetics Act and the Rules thereunder. Further this problem arises but rarely. It was therefore decided that the law should not be amended for dealing with an isolated problem.

- (ii) Shri Ashwani Kumar suggested that in cases where the Drugs Inspectors are themselves in a position to pinpoint the defect in drug preparations such as presence of fungus growth, foreign matter etc. or labeling defects, instead of sending the samples to the Government Analyst for reporting on the obvious defects the Inspectors should directly communicate such defects to the State Drug Control Authority for taking appropriate action. This procedure will save expenditure on sampling and also ensure early action.

The Chairman agreed that in such cases where the defects are evident, samples need not be drawn and departmental action can be taken depending upon the nature of the defects.

Item No. 29 : Issue of wholesale licences.

The Chairman pointed out that as there are no pre-requisite conditions for grant of a wholesale licence such as adequate space, employment of a

qualified person etc., the wholesale dealers are indulging in many malpractices.

The Director Drugs Control, West Bengal suggested that adequacy of space should be provided as one of the conditions for the grant of wholesale licence.

The Director, Drugs Control Administration, Gujarat stated that besides adequacy of space, working hours of the premises should be specified and the premises in respect of which wholesale licence is granted should not be located in a residential building and in any case should be separated from the living area. The premises should be equipped with proper storage conditions. It should also be known who the competent man for running the business is and as to the periods during which he would be available.

The Joint Commissioner, Food & Drugs Administration, Maharashtra stated that in Bombay there was an acute shortage of space. This fact should be taken into consideration.

After discussion, the Committee agreed that the following pre-requisite conditions for the grant of wholesale licences should be laid down :-

1. The premises in respect of which wholesale licence is to be granted should have an area of not less than 100 sq. ft. This will be considered as adequate space.
2. The premises should be in charge of a competent person, who should have passed the matriculation examination or its equivalent with 4 years experience in dealing in drugs.
3. The premises should be equipped with proper and adequate storage conditions.

Item No. 30 : To consider the extent of relaxation that could be permitted to under-developed States regarding enforcement of the amended proviso under Rule 71, 71-A and 76 of the Drugs & Cosmetics Rules, 1945.

This item has already been discussed vide Central Item No. 12.

Item No. 31 : To consider amendment to Second Schedule of the Drugs & Cosmetics Act, 1940 in respect of item No. 2, 3 & 5 as provided under Section 8(2) and 16(2) of the said Act.

The Drugs Controller, Orissa pointed out that in the Second Schedule for Immuno Biologicals it has been laid down that they comply with standards maintained at the Serum Institute, Copenhagen. Most of the products that are manufactured in the country conform to the standards maintained by

the Central Research Institute, Kasauli. He felt that products manufactured according to C.R.I.'s standards do not have the backing of the law. He desired that the Second Schedule should be amended appropriately and consequent amendments in Rule 124 should also be incorporated.

The Committee agreed to the suggestion.

Item No. 32 : Standard of drugs which are included in other Pharmacopoeias and also in I.P. – Testing Procedures to be followed.

The Drugs Controller, Kerala desired to know the Pharmacopoeia according to which a drug given both in B.P. and I.P. should be tested by the Govt. Analyst.

The Chairman clarified that under the Drugs & Cosmetics Act, the Indian Pharmacopoeia is the sole book of standards for drugs included in it. However, State Drugs Controllers may permit a drug include in I.P. to be manufactured and labeled according to B.P. or any other Pharmacopoeia for export purposes and in some exceptional cases for some special reasons, even for marketing in the country. It was therefore agreed that the Govt. Analyst should test the sample according to the claim made on the label but draw the attention off the State Drugs Controllers to the fact that the drug is included in the I.P.

Item No. 33 : Whether licence for manufacture is required for Blood Banks in mobile vans.

The Commissioner, Food & Drugs Administration, Maharashtra stated that mobile vans are not licensed in his State, as they only collect blood. After some discussion, the Committee felt that mobile vans do the work of collection of blood for the main Blood Bank and if the main Blood Bank has been licensed there is no need to licence the mobile vans used by them separately.

Item No. 34 : Grant of loan licence for repacking of drugs.

The Deputy Drugs Controller, Delhi Administration, stated that the Rules were silent on the issue of loan licences for repacking of drugs. He wanted to know whether a loan licence can be granted to an applicant in Form 25-A to repack drugs if the manufacturing firm holding licence in form 25 is permitted to repack drugs.

The Committee was not in favour of grant of loan licences for repacking of drugs, as the object of the loan licensing system is essentially to assist new entrepreneurs to market their products, both formulations and basic

drugs by utilizing the surplus capacity of actual manufacturers. till such time as they are in a position to set up their own units for actual manufacture of these products. In the case of basic drugs, however, a decision had, been taken earlier that no loan licence should be issued for the manufacture of any basic drug, if any imported materials are required for the purpose vide minutes of the 16th meeting of the Drugs Consultative Committee.

Item No. 35 : Exemption in Schedule K of Veterinary Surgeon proposal to amend Entry 6.

The Committee agreed that Entry 6 in Schedule K, relating to 'Medicines supplied by a Veterinary Hospital or by a Veterinary Surgeon' should be amended to bring it in line with the Entry '5' of the Schedule so far as extent and conditions of exemption are concerned.

Item No. 36 : Repacking of drugs.

The Drugs Controller, Andhra Pradesh stated that the list of items recommended for being repacked by the Drugs Consultative Committee earlier needs to be revised as certain preparations e.g. Tincture Iodine I.P., Tincture Benzoin, ointment of Turpentine etc. may lose their alcohol content during repacking.

The Chairman clarified that these items are generally required by small dispensaries in small packs and are marketed by the actual manufacturers in big packs only. If these items are removed from the list, they will not be available.

The Committee then decided that no change should be made in the 'List of drugs to be repacked.'

Item No. 37 : Manufacture of sub-therapeutic formulations.

The Drugs Controller, Andhra Pradesh stated that as per the Indian Pharmacopoeia, the strength of any drug to be manufactured is as per the usual strength given therein. Some of the manufacturers are however manufacturing and marketing the same drugs under patent and proprietary names with half the strengths of I.P. Thus Ampicillin caps. For which usual strength is 250 mg. are being sold in 100 mg strength. Tetracycline Hcl. for which usual strength is 250 mg. are also available in 100 mg strength as capsules. He desired that such sub-therapeutic preparations should be stopped.

A view was expressed that marketing of such preparations in lower strengths may be for used of children. The Director of Drugs Control,

West Bengal and Dy. Drugs Controller, Delhi said that in the case of paediatric preparations a decision has already been taken. The size of the paediatric tablets and capsules should be distinctly small than those intended for adults and former should be labeled with the legend "For Children's use only."

The Chairman stressed the need for enquiries that pharmacopoeial preparations are manufactured in the 'Usual Strength' given in the respective Pharmacopoeias. He stated that the main problem in many of the states is that when an application for a manufacturing licence is received, there are a large number of items included in the list accompanying the application. The licensing authorities who sign the licence do not ensure whether all the items in the list are according to the prescribed standards. He therefore, suggested that all items in the list should be properly screened so as to eliminate marketing of sub-therapeutic formulations.

It was also decided that the Chairman should recirculate the decisions taken in regard to the marketing of paediatric preparations.

Item No. 38 : Rule 63: regarding submission of application for renewal.

The Drugs Controller, Andhra Pradesh stated that for renewal of licence under the Drugs & Cosmetics Act & Rules the date of receipt of Challan is being recognized as the date of submission of the application. Even if the application for renewal of a licence is received after a month or so after the expiry of the licence, no penalty is being insisted upon in Andhra Pradesh if the Treasury Challan for payment of renewal fee had been received in time. But the audit deptt. is insisting that even in such cases penalty should be levied. He wanted to know the Committee's views in this regard.

The Committee agreed with the view expressed by the Chairman that the date on which application complete in all respects has been received should be taken as the date on which 'the application for renewal of licence has been made.'

Item No. 39 : The Drugs Controller (India) has issued a circular for withdrawing two types of formulations viz. (i) formulations containing Corticosteroids with Anti inflammatory agents and analgesic and (2) formulations containing Halogenated Hydroxyquinolines with Vitamins, Enzymes etc.

These items have already been discussed vide Items Nos. 13 & 14 of the Agenda.

Item No. 40 : Recently an amendment to the Drugs & Cosmetics Rules is made in respect of Public Laboratories. They are now required to get approval from the licensing authority in Form 37 by making an application in Form 36. This issue needs discussion as far as Drugs Laboratory of one State is to be approved by other States. The issue of approving Government Laboratories also needs consideration.

The Chairman clarified that once a laboratory is approved by a State Drugs Controller, it is approved for all the States and there is no question of their getting the approval from each and every State Government. The products manufactured in a particular State should preferably be got tested in the same State. If a particular approved laboratory in a State does not possess the necessary facilities for testing certain drugs for want of sophisticated equipment etc., samples of such drugs could be permitted to be got tested by an approved laboratory in another State.

The Deputy Drugs Controller, Delhi Administration said that Haryana State has an approved laboratory in Chandigarh, and enquired whether there is any objection to samples from Haryana being got tested in Delhi. The Chairman stated that there could be no objection to it. The Chairman agreed with the Director, Central Indian Pharmacopoeia Laboratory, Ghaziabad that as far as possible Govt. laboratories should not undertake private testing.

Item No. 41 : Rethinking on continuing to grant loan licences to manufacture drugs on loan licence basis is necessary and therefore it should be discussed in the meeting.

The Director, Drugs Control Administration, Gujarat stated that in order to curb unhealthy competition, it should be considered as to whether the provisions relating to grant of loan licences should be deleted from the Drugs and Cosmetics Rules, 1945 or else a provision should be made in the Rules to restrict the number of such licences that could be sanctioned in favour of any firm. He said that 'loan licensing' had been discussed at various Drugs Consultative Committee meetings and certain decisions had been taken, which have however, no legal backing. It was initially encourage because there was lack of utilization of capacity for manufacture; subsequently it was controlled and only people who had background knowledge were allowed to utilize the spare capacity and later on it was decided that not more than 6 units should be licensed on one premises and the number of items should also be restricted to 15. He expressed difficulty in controlling the loan licensing in Gujarat State. He also stated that the person or the firm who manufactures drugs on loan licence is the least responsible and he does not also in some cases possess testing facilities in the premises where the drug is manufactured. He

desired that clearcut guidelines should be laid down under the Rules in this regard.

The Chairman said that earlier the proposal to stop loan licensing was taken up with the concerned Ministries and it was decided that loan licensing should continue. He suggested that a small group may study the various problems involved in the system of granting loan licences and suggest the controls that should be exercised to remove unhealthy competition and ensure the quality of drugs manufactured against such licences, as also the period upto which a loan licence could be granted to a firm and furnish its report within six months.

The Committee agreed to the suggestion of the Chairman and a Sub-Committee consisting of the following persons was set up to study the problems created by the Loan Licensing System and suggest the changes that should be made in the Drugs & Cosmetics Rules with appropriate Draft Rules wherever necessary to achieve the objective outlined by the Chairman :-

1. Director, Drugs Control Administration, Gujarat.
2. Joint Commissioner, Food & Drugs Admn., Maharashtra (Shri Deshmukh).
3. Director of Drugs Control, West Bengal.
4. Deputy Drugs Controller, Delhi Admn.
5. Deputy Drugs Controller (India), West Zone, Bombay.

The Committee desired that the report of the Sub-Committee should be made available within 6 months.

Item No. 42 : Consideration of granting permission to manufacture Primaquine tablets with more than 2.5 mg base.

The Chairman clarified that necessary advice in the matter has already been circulated to the States after referring the matter to the Director, National Malaria Eradication Programme and obtaining his expert advice in this regard vide Circular letter No. X-11022/7/77-D dated 2nd June, 1978.

He therefore said that no further change can be made in the decisions already reached in the matter.

Item No. 43 : Consideration of the question of procuring testing methods for patent and proprietary medicines from the manufacturers by Govt. Drugs Laboratory.

The Director, Drugs Control Admn., Gujarat stated that considerable difficulties are faced when a patent and proprietary medicines is sent to the Government Analyst for test without giving the methods of analysis. He suggested that before licensing of patent and proprietary medicines, the licensing authorities should obtain from the manufacturers complete details of the methods of their analysis and should forward these to the Government Analyst while sending samples of such formulations for test.

It was agreed that the methods of test and analysis should be called for from the manufacturers by the State Licensing Authorities in respect of Patent & Proprietary medicines already licensed for manufacture. If the firm fails to furnish them permission granted for manufacture of the products concerned should be withdrawn. It was also agreed that while considering applications for grant or renewal of licences the licensing authority should call for the testing methods of patent and proprietary medicines and unless they are furnished, the licence should not be granted or renewed.

Item No. 44 : Inclusion of standards for Bandage cloth and Absorbent Gauze in the New Schedule to the Drugs & Cosmetics Rules.

The Drugs Controller, Uttar Pradesh suggested that standards for Bandage cloth and Absorbent Gauze may be incorporated in a new Schedule to the Drugs & Cosmetics Rules so that legal action could be taken wherever warranted.

The Chairman explained that bandages are manufactured by small manufacturers. There are I.S.I. specifications for these, but if they are required to comply with these standards, the bandages become 3 to 4 times costlier and it will be difficult for the hospitals with their limited budget to afford their purchase. So some manufacturers in Meerut were asked to supply samples of three different qualities of bandages. These have got examined in hospitals and by the Drugs Laboratory, Baroda. Based on the reports received from the Hospitals about the performance of these bandages and the reports of the Baroda Laboratory, standards are being laid down by a Sub-Committee of the Drugs Technical Advisory Board. The Sub-Committee is expected to meet shortly to finalise these standards. The Chairman said that till such time as these standards are prescribed under the Rules, the Drugs Control Authorities need not adopt a strict attitude in the matter.

Item No. 45 : Proposal for revision of Schedule P of the Drugs & Cosmetics Rules – Date of expiry of drugs.

The Commissioner, Food & Drugs Administration, Maharashtra stated that Schedule P at present includes drugs like antibiotics, Vitamins, Sera

and Vaccines. It does not include new antibiotics and their combinations which are available in the market. He suggested that Schedule P of the Drugs & Cosmetics Rules should be revised suitably so as to include all new combinations of antibiotics, vitamins and other drugs of a thermolabile nature which are likely to deteriorate on storage.

The Chairman clarified that by a recent amendment of Rule 96 (as published under G.S.R. 19 dated 15/12/77 in the Gazette of India, Part II, Sec.3 Sub-Sec.(i)) drugs specified in Schedule C (1) and their preparations including combinations with other drugs are required interalia to bear on the labels (a) the date of manufacture, and (b) the date of expiry of potency fixed by the manufacturers.

He, however, agreed that the life period of drugs as given in Schedule P has to be scrutinized in the light of more recent data regarding their stability and needed revision in the case of some items. He requested the State Drugs Control authorities to furnish their comments on the life period of items included in Schedule P and other items that are being marketed as per the information available with them so that the question of revision of Schedule P may be considered.

Item No. 46 : Ban on the use of Saccharine in the manufacture of Gripe Waters Mixtures.

The Committee unanimously decided that the use of Saccharin should not be permitted in any paediatric preparation.

Item No. 47 : Marketing of hard gelatin capsules containing antibiotics and other life saving drugs in polythene bags.

It was decided that the Sub-Committee constituted under item 3(b) to consider the question of use of polythene containers for packing of oral liquid preparations may also consider the suggestion made under this item by the Deputy Drugs Controller (India), Bombay.

Item No. 48 : Any other item with permission of the Chair.

(a) Checking the reuse of glass bottles for filling Transfusion solutions.

The Chairman explained that a survey on the type of bottles which are being reused by manufacturers of Transfusion solutions was carried out by the Deputy Drugs Controller (India), South Zone, Madras. The survey has revealed that reuse of glass bottles both USP Type II and Type I (of other manufactures) is widely prevalent. He said that to check the reuse is a difficult problem but some way has to be devised to minimize it. A circular No.15-65/77-DC dated 20/5/78 has already been issued in this

regard. But there are two factors involved namely availability of the transfusion bottles and their price.

The Drugs Controller, Andhra Pradesh admitted that in his State manufacturers were reusing glass bottles under the plea that if fresh bottles were to be used it would increase the price. The Drugs Controller, Goa suggested that if data regarding the number of bottles required and the type of glass was available. The question of making the required number of bottles available to the drug industry would be tackled.

The Committee agreed that all State Drugs Control Authorities should collect and furnish the Drugs Controller (India) with the following information :-

- 1 Particulars of manufacturers manufacturing transfusion solutions.
- 2 No. of bottles used per annum.
(i) U.S.P. Type I (ii) U.S.P. Type II
- 3 Whether bottles are reused by them.
- 4 The number of bottles that will be required, re-use is not permitted and the likely, increase in the unit cost of the transfusion solution in that event.

(b) Facilities for test regarding sterility and absence of Pyrogen.

The Chairman said that it has come to his notice that some of the units manufacturing transfusion solutions do not have facilities of their own for testing sterility and absence of pyrogens, and they get these tests done from outside sources.

The Committee agreed with the Chairman that in the case of all parenteral preparations, the manufacturers should be required to have their own facilities for carrying out the tests for sterility. Besides, in the case of transfusion solutions and other large volume injectable products requiring to be tested for absence for pyrogens, it should be insisted upon the manufacturers to have their own facilities for testing for absence of pyrogens.

(c) Discretionary powers to cover items like Castor oil Benzyl Benzoate etc. sought in regard to qualification of competent technical staff as provided for certain other items in the proviso to Rule 71(1).

Shri Shastri, Director, Drugs Control Admn., Gujarat said that in Gujarat there are a number of manufacturers who are manufacturing Castor oil and Benzyl Benzoate etc. They want to market their product as basic chemicals. He suggested that as in the manufacture of these items much knowledge of pharmaceutical chemistry is not necessary, they may be

included in the same category of items as mentioned in the second proviso to Rule 71(1) and the licensing authority given discretionary powers.

The Chairman stated that certain items like Medical Oxygen mentioned there in required a specialized technique. The requirement of experienced chemical engineer stands already approved. If Shri Shastri needed any other qualifications for competent technical staff for the manufacture of the items mentioned by him, he could write to him separately in the matter.

(d) Printing of high prices by small scale units.

The Director, Drugs Control Administration, Gujarat pointed out that the prices marked on the products manufactured and marketed by small scale units are found to be much higher than those of similar products manufactured by large scale manufacturers. He wanted to know how this anomaly could be removed.

The Chairman clarified that under the existing Price Control Order firms having an annual turnover of less than 50 lakhs do not require their prices to be approved by Government, with the result they are allowed to charge any price they want. He informed him that under the New Drug Policy, prices of certain specified drugs in categories I and II will be regulated according to the Leader Price and Leader Prices will be applicable to the Small Scale Units as well. As far as products in Category III are concerned the small scale units will be exempted from Price Control, if their turnover is less than Rs.50 lakhs per annum.

(e) Physician samples not intended for sale.

The Director, drugs Control, West Bengal stated that some shops were found stocking physician samples and their licences were suspended for ten days. He wanted to know as to how the stock of physician samples should be disposed of after the expiry of 10 days.

The Chairman said that they could be destroyed.

It was tentatively decided that the next meeting of the Drugs Consultative Committee should be held in Bangalore.

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