MINUTES OF THE 19TH MEETING OF THE DRUGS CONSULTATIVE COMMITTEE HELD AT NEW DELHI ON THE 12TH & 13TH APRIL, 1976

The Chairman, Dr. S. S. Gothoskar, welcomed the members of the Committee and expressed his deep appreciation at the excellent co-operation received from them since the last meeting took place. On the part of the Central Drugs Standard Control Organisation, he assured the members that the Central Drugs Standard Control Organisation was willing to extend whatever assistance it could to the States.

Giving his impressions of the effects of the Emergency, the Chairman stated that the Emergency has played a notable part in bringing down the incidence of spurious drugs. He recalled the decision taken at the last meeting of the Committee that the State Drugs Control Authorities should conduct surveys in their respective States to assess the quality of drugs moving in the market and mentioned that the North Zone office of the Central Drugs Standard Control Organisation had carried out a survey in covering about 64 small towns in the zone. A similar survey was carried out by the Delhi Drugs Control Adminstration also which indicated that out of 300 and odd samples of drugs drawn and tested not even one sample was found to be spurious. He requested the State Drugs Control authorities to complete the surveys launched by them to the extent possible and convey the results expeditiously. He said that the result of these surveys would help in rebutting the charge that spurious drugs were widely prevalent.

As regards drugs reported upon as spurious by Government Analysts, the Chairman mentioned that follow up action on such reports was taken directly by the Central Drugs Standard Control Organisation at the Headquarters with the concerned State Drugs Control authorities and desired that the action taken by them on these should be intimated to the Central Drugs Standard Control Organisation. Even if attempts to trace the manufacturer of the spurious drug are not successful, the dealer could always be preceded against in such cases. It was agreed that with a view to ascertaining the action taken on reports relating to spurious drugs, the Drugs Controller, India would hereafter issue a telex or telegram in the first instance and follow it up by a d.o. reminder to the concerned State Drug Control Authority. The members agreed to expedite the information wherever called for from them in this regard.

The Chairman stated that with a view to meeting the anticipated increase in the incidence of malaria during the coming monsoon season, the State Trading Corporation has been directed to import larger quantities of chloroquin phosphate for supplementing the indigenous production. He requested the members to ensure that the bulk drugs released to manufacturers are processed into tablets immediately and the finished drugs are made available in the market. It was agreed that State Trading Corporation would furnish to the State Drug Controllers a monthly statement regarding the release of chloroquin salts made to manufacturers in their States to enable them to exercise necessary checks in this regard and furnish the Drugs Controller, India with information

about the quantities of chloroquine preparations manufactured and supplied by units in their States.

The Chairman informed the members that a scheme for extending financial assistance to States for strengthening their food and drug testing laboratories has been cleared by the Planning Commission and the Ministry of Finance. Letters have been issued by the Department of Health to State Governments in this regard. He desired that State authorities should ensure that the funds made available for strengthening the testing laboratories should be spent. He agreed to invite the concerned Under Secretary, Shri Ramesh Bahadur, in the Department of Health for enlightening the members on the financial and budgetary procedures involved in implementing the scheme. A resume of discussions which followed in this connection is attached vide **Appendix II**.

The Chairman then referred to the facilities for Radiation Sterilisation available in the ISOMED DIVISION of the Bhaba Atomic Research Centre at Trombay and suggested that members visiting Maharashtra State should visit this unit. As Radiation Sterilisation is the best method of sterilization for surgical dressings packed in small packings, manufacturers of surgical dressings should be prevailed upon to avail of the facilities at ISOMED. For ophthalmic ointments also there is no other efficient way of sterilization than by radiation and certain units are already making use of this.

Shri Rangnekar stated that in Maharashtra State it is compulsory for the manufacturers to have ophthalmic ointments sterilized by radiation. He suggested that the next meeting of the Drugs Consultative Committee may be convened in Bombay so as to provide an opportunity to the members to visit the ISOMED Division. This suggestion was agreed to by the Committee.

The Chairman then sought the assistance of the members in compilation of the All India List of Licensed Drugs Manufacturers and requested them to furnish 100 copies of the list of licensed Drug Manufacturers in their respective States. This would facilitate compilation of the All India list by the Centre which could then be circulated to the State Drugs Controllers and the All India Chemists & Druggists Associations for guidance. The members agreed to the Chairman's request.

The Chairman brought to the notice of the members that information for the Annual Report for 1974-75 was still awaited from certain States and in particular Andhra Pradesh, Assam, Bihar and Madhya Pradesh. In view of the importance of this information, he requested the members to expedite its submission.

The Chairman drew the attention of the members to the fact that printed copies of the inspection book in Form 35 of the Drugs and Cosmetics Rules, which have to be made available by the licensing authority to the licensees have not been provided by some of the States. He suggested that the authorities who have not so far provided the inspection book should fulfill this statutory requirement. They may if necessary, ascertain from the Drugs Controller, Karnataka State the type of inspection book that has

been provided by him. Urgent action should be taken in this regard as the Inspector has to record his impressions of inspection in this Book.

The Chairman then invited general comments from members briefly highlighting the achievements/activities in respect of their States before proceeding with the agenda proper.

ANDHRA PRADESH

Giving the existing set up of the Drugs Control Organisation in his State, Shri Rama Rao stated that 5 posts of Drugs Inspectors are vacant and are being filled up. There is no legal-cum-intelligence cell in the State. There is a Drug Testing Laboratory which tests only non-schedule C & C1 drugs. Biological products are got tested from the Drugs Laboratory. The State Government have plans to develop the laboratory. Central assistance has been welcomed in this regard. Rules relating to Ayurvedic (Unani) & Siddha medicines have not been enforced so far, as the decision regarding the enforcement authority for the purpose is yet to be taken by the State Government. The Director of Medical and Health Services had, however, been notified as the licensing authority in respect of the Indigenous System of Medicine.

BIHAR

Dr. Y. K. Sinha stated that since 1974 they have an independent State Drug Controller in the Department of Health of the rank of Joint Director of Health Services. There is a Drugs Inspector for each district in the State with clerical staff attached to him. He thanked the Government of India for assistance in setting up a combined Food and Drug Laboratory in Bihar State. The State Government have already drawn up plans for the building and is taking up steps for acquisition of land and the construction work soon. Enforcement of control on Ayurvedic drugs was started in February last. 119 applications for grant of licences for manufacture of Ayurvedic and Homoeopathic medicines were received against which 9 licences for homoeopathic medicines were granted and the remaining applications were being processed. Advisers in Ayurveda and Homoeopathy are consulted for issuing and canceling such licneces. As for manufacture of allopathic drugs, there are 147 licensees in the State. 14 manufacturing licences were cancelled, one licence was suspended and two manufacturers were prosecuted during the last year. Dr. Sinha stated that they have a vigilance cell for tackling the problem of spurious drugs and Flying Squad is attached to it. He is also getting assistance from the East Zone. After he had taken over charge, the licences of 14 wholesalers in one area who were dealing in spurious drugs had been cancelled. He agreed with the Chairman that emergency has had a salutary effect on the drug industry and trade and has helped in the enforcement of Drugs and Cosmetics Act and the Drugs (Prices Control) Order.

GUJARAT

Shri Shastri stated that they have an independent Directorate of Drugs Control in Gujarat and the administration of Prevention of Food Adulteration Act is also being

transferred to the Drugs Control Department shortly. The total number of posts in the Department is 478, of which 240 are on the administrative side and 238 on the testing side. They have a separate intelligence wing attached to the Department. There are about 538 manufacturing units in all located in the State and **665* manufacturing licences have so far been granted. 300 applications have been received for grant of licences for manufacture of Ayurvedic medicines of which 138 applications have been disposed of. Only one licence for manufacture of homoeopathic medicines has been granted in the State. With the assistance of the Intelligence Cell, 38 prosecutions in respect of spurious drugs were launched, of which 23 have resulted in conviction and 15 cases are yet to be decided. He stated that the modus operandi of spurious drug manufacturers has changed and they now market such drugs through private medical practitioners.

Shri Shastri stated that a study on the presence of particulate matter in injectible preparations is being made as to locate the cause for the same and a report on the study when completed will be furnished. Shri Shastri informed the committee that the facilities for testing of drugs at the Drugs Laboratory, Baroda are already being availed of by various States e.g. Delhi, Jammu and Kashmir etc. and that applications for similar assistance from other States including Kerala & Rajasthan are also being considered by the State Government.

Shri Shastri desired that the price of chloroquin should be fixed uniformly so that the supply position could be maintained.

Referring to sterilization facilities at ISOMED DIVISION, he said that they had come across contaminated samples of drugs which were sterilized there but said that it was possible that the samples under reference were already defective. The Chairman remarked that sending of samples for sterilization at ISOMED does not imply that the manufacturer need not test such samples at his level. He stressed on the necessity of sterility tests being done by the manufacturers before releasing the stocks for sale.

Shri Shastri also stated that they have an up-to date list of licensed drug manufacturers in Gujarat and that addition and deletions to the list have been notified by them.

** The figure seems to be incorrect*

KARNATAKA

Shri K. N. Shanbhogue stated that the ten golden principles earlier publicized by them in canarese and observance of which minimize instances of spurious and sub-standard drugs have now been rendered into English and given vide publicity.

He stated that his Department has a library which contains 20 films relating spurious drugs, the duties and responsibilities of Drug Control Department, the obligations of Industry, the trade and consumer etc. These films were being exhibited intensively to educate the general public.

The Karnataka State Drug Control Department was giving intensive training to Graduate Pharmacists in quality control and manufacture of drugs. The period of training is 18 months. The trainees also receive stipends from Government as well as manufacturers. The Scheme forms part of a Job Oriented Programme.

He mentioned that they have come across instances where certain racketeers gain confidence of the parties in the first instance by supplying quality bulk raw materials and then pass off spurious drugs. He, therefore, cautioned the members against such tricksters and desired that manufacturers should do intensive inspection of such materials.

He thanked the Government of India for the financial assistance for development of the State Drugs Testing Laboratory. He stated that Divisional Officials of Drugs Control in Karnataka have been provided with transport facilities. He has got an order issued by the Government of Karnataka empowering Drug Control Officers to go and draw samples from Government Medical Institutions/stores and colleges. Though no prosecutions can be launched, such inspections have a salutary effect.

He stated that they have been receiving excellent co-operation from the Zonal Officer in the South Zone of the Central Drug Control Organisation and that they also co-operate with him in matters relating to quality control on drugs.

RAJASTHAN

Dr. Purohit informed the committee that the strength of Drug Inspectors in Rajasthan has been raised from 6 to 15. The State Government have also appointed some Dy. Chief Medical & Health Officers as ex-officio Drugs Inspectors. He expressed difficulty in carrying out survey of prevalence of spurious drugs in the State in view of the meager number of Drug Inspectors and in-adequate testing facilities. He desired that the Gujarat and Maharashtra should assist Rajasthan by undertaking to test a fixed number of samples of drugs every month, which they should indicate. He felt grateful to the Centre for the proposed assistance in the establishment of a laboratory in Rajasthan.

Dr. Purohit expressed that during past one or two years the State Government had experienced a great shortage of chloroquin and that MMEP did not supply even 50% of their requirements. On the other hand certain manufacturers were able to produce 4 times their normal output of chloroquin tablets which idicated that they were able to procure the bulk from sources other than the S.T.C. He felt that check should be exercised on the proper utilization and distribution of the drug. Dr. Purohit stated that in several parts of Rajasthan, Medical facilities have been provided at places where population is below 2000 or even 500. There are, however, no chemists shops. These are desert/remote areas and people are reluctant to operate. People in these areas have to be assisted with medical aid and drugs. He desired that drugs in unopened containers should be allowed to be sold there by unqualified persons on the prescription of non-medical persons. Drugs Controller, Himachal Pradesh suggested that the services of Red Cross Stores could be availed of in such remote areas as is being done in Himachal Pradesh.

Dr. Purohit informed the committee that a Drugs Advisory Committee has been set up under the Chairmanship of Health Minister of State which includes representatives of industry, the trade, Drug Controller of the State etc. to understand each other's problems and advise in the matter. He expressed the hope that when full complement of Drug Inspectors is in position, it would be possible for the State to undertake work relating to the enforcement of laws and surveys more effectively.

UTTAR PRADESH

Dr. Gujral stated that after Kanpur episode they have been able to get additional posts of one Law Officer and one Asstt. Controller for drugs and food. A Drug Advisory Board at the State level has also been constituted.

He spoke of the prevalence of spurious drugs particularly in interState trade. Although this was not alarming, he stated that so far as his State was concerned he was getting excellent co-operation in tracking down such cases from the Asstt. Drugs Controller (India), North Zone, Ghaziabad.

Dr. Gujral expressed difficulties in licensing firms for manufacture of Ayurvedic and Unani medicines on the one hand and homoeopathic medicines on the other. He stated that the number of Ayurvedic and Unani manufacturers in the State was very large. In the case of homoeopathic medicines as there were no specific standards for them, the State Government were not in favour of licensing Homoeopathic drug manufacturers.

The Chairman stated that while it is true that Ayurvedic and Homoeopathic medicines cannot be tested adequately as allopathic medicines, the object of exercising a control over these medicines was at least to ensure that the manufacturing operations are done under proper conditions. Dr. Gujral stated that they have a food laboratory at Lucknow and a drug testing laboratory at Varanasi but these laboratories are ill-equipped. The State Government purchases Rupees 4.5 crores worth of drugs every year and wants that all samples should be got tested. The problem is one of lack of adequate capacity for testing available with the State Government. He thanked the Central Government for financially assisting the State for setting up a new combined Food & Drug Laboratory in the Fifth Plan Period.

He desired that interState movement of pethidine should be so streamlined that there is no shortage in U.P. Chairman stated that as long as the Excise Commissioners of the concerned states are agreeable, there should be no difficulty in the interState movement of pethidine. Besides, M/s Gluconate have again gone into production and small additional requirements could also be arranged from the firm according to the prescribed procedure.

Dr. Gujral desired to know the procedure that should be followed in regard to licensing of Blood Bank, and Government institutions manufacturing transfusion solutions. Shri Rangnekar stated that in Maharashtra the State Government have issued

orders that Blood Banks must comply with the Drugs and Cosmetics Rules and that Drugs Inspectors can draw samples from Blood Banks in the State at any time.

The Chairman said that there is nothing which may prevent a Government Institution from being licensed. The only thing is that if a hospital manufactures for its own use, it may not require a licence. If the drugs manufactured are for sale, the institutions will have to be licensed.

WEST BENGAL

Shri Amal Chakravarti stated that a Drug Advisory Board is functioning in the State, which has met five times so far.

The Drug Control Administration in West Bengal is being strengthened. In this connection a committee had been appointed to go into the activities of the department and its report is under consideration of the West Bengal Government. The State Government, he said, have already passed orders for the amalgamation of the Food Laboratory in Calcutta with the Drugs Control Laboratory of the State Government.

Shri Chakravarti said that they were already licensing homoeopathic units in their State and from 12th July, 1975 have started enforcing the provisions relating to Ayurvedic & Unani drugs. 500 applications have been received for manufacture of Ayurvedic drugs, against which 100 licences have been issued and the remaining applications are being processed.

He stated that after the West Bengal Drugs Amendment Act was passed, the incidence of spurious drugs has come down for fear of penalty of life-imprisonment now provided under the amended Act. A survey on the prevalence of spurious drugs has also been conducted and results of the survey are still awaited.

Shri Chakravarti pointed out that abortificient preparations manufactured in other States were pouring into West Bengal while West Bengal has banned their manufacture. The manufacturers in West Bengal were, therefore, protesting that either a uniform policy should be followed on the subject or they should not be subject to discrimination.

The Chairman pointed out that we have already decided to ban manufacture of abortificient preparations at an earlier meeting of the committee and requested the members to strictly implement the decision of the Committee.

As regards availing of the sterilization facilities at ISOMED DIVISION, he stated that ISOMED would be putting up a plant in Calcutta, sometime next year. Then these facilities would be availed of by the manufacturers in West Bengal. Shri Chakravarti also informed the members that a committee has been constituted in the State to carry out a survey on the extent of use of psychotropic substances and suggest measures for restricting their use. He also informed the members that the Government of West Bengal

have asked all blood banks in hospitals to take licences under the Drugs and Cosmetics Rules.

TAMIL NADU

Shri C. V. Narasimhan stated that the Drugs Controller of the State is assisted by a Joint Drugs Controller & 2 Asstt. Drug Controllers, 59 Inspectors and 10 Senior Inspectors. There are 423 manufacturing licensees and 9000 sales concerns.

Hospitals and hospital pharmacies are being regularly inspected, purchases made are checked and samples drawn from them in doubtful cases. During these inspections, cases of pilferage of drugs have come to light and necessary action taken. It is also proposed to enact a law on the basis of the Kerala enactment regarding pilferage. Cases have also come to notice where certain dealers have charged higher prices to hospitals than permissible under the Drugs (Prices Control) Order and such parties are being prosecuted.

The Government of Tamil Nadu are constructing a Drug Testing Laboratory at Madras and the ground floor of the building will be ready by June, 1976. Government have sanctioned Rs.5 lakhs on capital account and Rs. 1 lakh for purchase of equipment in the first instance. A further sanction of Rs.6 lakhs for construction of the first and second floors and of Rs. 2 lakhs for purchase of equipment has been received.

A survey on the misuse of psychotropic drugs by inspecting shops located near schools and colleges was under taken and it was found that 30% of the sale of such drugs was across-the-counter in an unaccounted manner. Dealers have been warned against such sales in future and have now given an undertaking in this regard. This has prevented unaccounted sale of psychotropic substances in the State to a large extent.

Shri Narasimhan also informed the committee about the survey carried out by his administration with Police help. On unaccounted sales of pethidine, it was found that pethidine was available to interested doctors for supply to addicts. During the survey, a stock of 4000 ampoules of pethidine clandestinely suppressed by a dealer in collusion with a doctor for being passed on to addicts was recovered. The licence of the chemist was cancelled and both the dealer and the doctor are being prosecuted under the Dangerous Drugs Act.

Rules relating to control over manufacture of Ayurvedic and Unani medicines have not yet been enforced and the matter is under consideration of the State Government. Shri Narasimhan then referred to the prosecutions launched in his State against manufacturers of so called Ayurvedic drugs viz. Arishtas and Asavas containing chloral hydrate. Though the accused contended that these were Ayurvedic drugs over which the State had not yet started control. The court had held that these were (allopathic) 'drugs' & convicted the accused.

Shri Narasimhan requested for assistance to his State Drugs Laboratory. The Chairman suggested that he should make a reference in the matter to the Centre, as the State Laboratory has already been started.

HARYANA

Dr. Chopra stated that in Haryana they have a compact State Drug Control Organiation at present and the State Government have proposals to augment the strength of the supervisory and other staff during 1976-77.

In the State, there are 137 manufacturers including 68 allopathic, 1 homoeopathic and 33 Ayurvedic manufacturers. A laboratory for testing food and drugs is located at Chandigarh. The State also utilizes the testing facilities of the Punjab University Laboratory and Shri Ram Testing House, New Delhi. Dr. Chopra desired that a building should be provided for the State Laboratory. He, however, welcomed the Central assistance for purchase of equipment.

A Drug Advisory Board has been constituted in the State and a meeting of the Board has been held. Dr. Chopra said that all new manufacturing firms in the State are got, jointly, inspected by the North Zone Office and his officers.

Dr. Chopra stated that over the past one year they have been experiencing shortages of some drugs viz. morphine, pethidine, glycerin, aspirin and anaesthetic etc. He agreed with Dr. Gujral that restrictions on interState movement of narcotic drugs should be relaxed to make their supply position easier.

He pointed out that certain firms are marketing full sized capsules for paediatric use and stated that unless a uniform distinctive colour scheme and size pattern is evolved for paediatric capsules, people are likely to be cheated by unscrupulous dealers. He also mentioned that the increasing proliferation of small scale units is posing a problem on all fronts e.g. inspections, licensing, recommending raw materials and checking over quality. Where licences are refused in one name, these are attempted to be obtained under a different name. He desired that such mushroom growth of small scale units should be checked and directive given in this regard. The Chairman pointed out that units conforming to all the requirements cannot be refused a licence. Further, while the general policy of the Government is to encourage small scale entereprenures, it does not mean that units should be licensed at cost of quality.

Dr. Chandra stated that since 1969 when the definition of the term 'qualified person' under the Drugs Rules was amended, more applications for grant of wholesale licence as against retail licence have been received. But wholesalers actually do retail dealing. He was of the view that the erstwhile provisions should be reintroduced in the Drugs & Cosmetics Rules. He also desired that M.B.B.S. qualified doctors should be allowed to run pharmacies in addition to their normal medical practice.

HIMACHAL PRADESH

Dr. Grover stated that in Himachal Pradesh the Director of Health Services acts as the Drugs Controller and he is assisted by two Deputy Directors and two inspectors. One of the posts of inspectors was vacant. There were about 11 manufacturers, two Government institutions manufacturing Ayurvedic drugs and one cosmetics manufacturer. There was, however, no homoeopathic manufacturer in the State. Directorate of Ayurveda is separate from the rest of the Directorate of Health Services.

The State has a food laboratory which is being developed into a combined Food and Drug Laboratory with central assistance. The State Government have plans to strengthen the organization to enforce the laws relating to Food and Drugs Control stringently. 42 samples of drugs were drawn during the year for tests, of which 14 samples were found to be not of standard quality and 2 samples spurious. The parties dealing in spurious drugs were prosecuted.

TRIPURA

Dr. Chakrabarti stated that the Director of Health Services is the Drugs Controller. He is assisted by only one inspector at present. Two posts of Inspectors have been created and will be filled up shortly. All the sub-divisional medical officers are also functioning as ex-officio Drug Inspectors.

Samples of drugs are sent to Central Drugs Laboratory, Calcutta for tests. For lack of testing facilities in the State, Dr. Chakrabarti stated that they have not yet started enforcing the provisions relating to control over Ayurvedic and Unani drugs.

MEGHALAYA

Dr. O. Lyugdoh stated that in Meghalaya the Director of Health Services works as the Drugs Controller. He is assisted by one Asstt. Drugs Controller who is a non-medical person and by a Drugs Inspector. The District Medical Officers and Sub-Divisional officers help in issuing sale licences. There is only one manufacturing unit namely Pasteur Institute which is inspected with the help of the Zonal Officers of the Central Drug Standard Control Organisation. A committee constituted by the Government of India recently visited the Pasteur Institute and suggested increase in production of anti-rabies vaccine, during the Fifth Plan Period. Licensing of a Blood Bank in Meghalaya is receiving consideration. Applications for grant of licence to manufacture cosmetics have been received from individuals and these will be examined in consultation with neighbouring States.

Dr. Lyugdoh stated that certain manufacturers offered drugs for sale to hospitals at prices which ranged between the wholesale price and the retail prices and stated that Government should issue a clear directive as to the price firms can charge from hospitals.

ORISSA

Shri Pany stated that Drugs Control Department in Orissa is part and parcel of the Directorate of Health Services and is functioning under the charge of a whole time Drugs Controller. He is assisted by two Assistant Drugs Controllers and 16 Inspectors. During the year, a number of raids were carried out in the State in suspected areas and items such as spurious cosmetics purported to be manufactured in Calcutta and date expired drugs meant for sale were seized. Six prosecutions were launched and in three cases convictions were recurred.

The abuse of psychotropic drugs has been minimized to a great extent in the State with the co-operation of chemists, the doctors and the Medical Associations. Patients are required to have prescriptions, in duplicate, from the doctor. One is retained by the dealer for record and the other given back to the patient with the stamp "Supplied".

Shri Pany stated that the State has completed phase 1 of the new Drugs Laboratory at Bhubaneswar at a cost of Rs.16 lakhs and got Analytical personnel trained. The development of the laboratory still continues. While he thanked the Government of India for providing financial assistance for purchase of equipment, he desired that financial assistance should be given for the building also, the construction of which was still in progress.

Shri Pany praised the assistance he was receiving from the Dy. Drugs Controller, East Zone, Calcutta and desired that the Zonal Organisation should be expanded further so as to enable it to give further increased assistance.

He pointed out that there was shortage of Dapsone tablets in Orissa and desired that the manufacturers viz. Burroughs Wellcome should be prevailed upon to make the drug available. The Chairman clarified that M/s Burroughs Wellcome had huge pending orders from D.G.S. & D. and had so far been diverting the entire production to meet their committed requirements of Dapsone tablets. The position has now changed. M/s Burroughs Wellcome have started releasing 20% of their production in the market w.e.f. 1.4.1976. M/s Bengal Chemical and Pharmaceutical Works have also stepped up their production of Dapsone and their preparation is available in the market.

MAHARASHTRA STATE

Shri Bhirud stated that the total strength of the staff of the Food and Drugs Adminstration in Maharashtra State is 1275 of whom about 150 are on the administrative side and the remaining on the enforcement side.

During the year, about 2700 samples were tested and 25% of these were found to be not of standard quality. Increase in the percentage of sub-standard and samples was due to various factors e.g. rigidity in examination of samples for particulate matter, appearance of tablets etc. 261 cases were investigated during the year and 68

prosecutions launched for misbranded drugs and cosmetics. 45 cases have been decided, of which 36 cases resulted in conviction.

70 complaints of overcharging of drugs were received which were investigated and action in 37 cases was taken. Six cases resulted in conviction.

About 64,000 advertisements were scrutinized by the Administration under the Drugs and Magic Remedies (Objectionable Advertisement) Act. In two cases, prosecutions have been launched.

A committee has been formed for scrutinizing cases for prosecution in the State.

Shri Rangnekar suggested that the Zonal Offices of the Central Drug Standard Control Organisation should themselves make investigation into complaints received by them, prepare the entire case and then hand it over to State Drug Control Administration for launching prosecutions under the provisions of the Drugs and Cosmetics Act and Rules thereunder. The Chairman agreed to this suggestion.

Shri Rangnekar also desired that the Zonal Office should inspect the premises of suspected manufacturers whose particulars he could furnish to it.

KERALA

Shri Chandrasekharan Nair stated that manufacturers in Kerala State are reluctant to send their products to ISOMED for sterilization on account of problems of logistics.

He thanked the Central Government for financial assistance to their laboratory for purchase of equipment.

He observed that all findings cannot be recorded in Inspection Book in Form 35 and in particular those on which require further action / investigation is to be taken and cannot be disclosed to the licensee e.g. observations regarding stocks of suspected material.

In Kerala State, a survey has been carried out regarding the sale of psychotropic drugs and it was found that the incidence of abuse has come down sharply. Almost all sales are covered by prescriptions and dealers are required to maintain prescriptions.

He commended the co-operation and assistance which his State Organisation is recovering from Dr. Gupta, Asstt. Drugs Controller (India), South Zone, Madras. With the assistance of the Zonal Organisation, all hospitals whether Government or private have been inspected and conditions in the Hospital Pharmacy and stores have improved. As a result of these inspections, the State Government have directed that no sterile preparations should be manufactured in a hospital. Although sub-standard drugs are required to be sent back to the manufacturers concerned, it was surprising that some of these stock found their way back to some private hospitals.

He stated that Kerala has a State owned Drug factory at Allappy and this has also been inspected by the South Zone Officers of the Central Drug Standard Control Organisation.

He desired that some guidelines should be laid down for taking action under the Drugs (Price Control) Order, 1970 against dealers who overcharge 1 or 2 paise only on sale to customers, as in a few cases this has been found to be done deliberately.

Shri Rangnekar suggested that if a dealer repeatedly overcharges even 1 paise, he should be prosecuted.

The Chairman stated that the bonafides of the dealers, their past reputation and overall intention behind a particular instance of over-charging should enable the authorities to decide on the course of action. Even if 25 p. or more have been charged by an honest dealer through oversight, he could be warned only. On the other hand, if a dealer is over-charging repeatedly even to the extend of 1 or 2 paise then he should be prosecuted.

GOA

Dr. Frias stated that in Goa, the provisions of the Drugs and Cosmetics Act & Rules were being enforced since 1966. The Organisation has a wholetime Drugs Controller who is assisted by a Asstt. Drugs Controllers. The latter have also been notified as Drug Inspectors. Three additional post of Drugs Inspectors are also proposed to be created. The territory has in all 23 manufacturers and 300 sales premises. Two manufacturers have surrendered their licences and prosecution has been launched against 1 dealer for selling drugs after expiry of the licence.

As regards testing facilities, Dr. Frias stated that they are utilizing the services of the Drug Control Laboratory in Maharashtra State and the Central India Pharmacopoeia Laboratory, Ghaziabad. Out of 43 samples tested, 14 were found substandard but none was spurious.

He stated that in Goa, night sale and dispensing services are compulsory and chemists open shops during the night by turn.

Due to influx of hippies in Goa, there is a lot of consumption of psychotropic substances. A survey was carried out but it revealed that sales were covered by prescriptions. Possibly, there is collusion with the doctors.

He stated that Blood Banks were attached to hospitals and did not know whether to license them or not, as they did not charge for the blood but only for the service rendered. The Chairman stated that it was desirable that Blood Banks should be asked to take out licences.

Dr. Frias reported that there were shortages of drugs like Heaprin, Ephedrine, Pethidine and Lignocaine injections. Shortage of Lignocaine was hampering the family planning programme work.

As regards pethidine, the Chairman said that the requirements of Goa were very small and that Dr. Frias could approach M/s. Gluconate for supplies.

Regarding shortage of Lignocaine Injection, the Chairman said that there was only firm namely M/s. Suhrid Geigy manufacturing the spinal injection of Lignocaine for meeting the entire family planning requirements in the country. He requested Shri Rangnekar and Shri Shanbhogue to prevail upon some firms in their respective States to take up the manufacture of Lignocaine Spinal anaesthetic so that the Family Planning Programmes do not suffer a set back. The Drug Control authorities in Karnataka & Maharashtra States agreed to the suggestion. Dr. Frias also stated that there was no control over Ayurvedic medicines in Goa.

DELHI

Dr. Sharma stated that the Director of Health Services is the Drugs Controller in Delhi. He is assisted by a Deputy Drugs Controller, two Asstt. Drugs Controllers and 24 Drugs Inspectors.

Provisions of Chapter IV-A of the Drugs and Cosmetics Act have been enforced since May, 1975.

75 manufacturers in Delhi have been licensed including one Ayurvedic and one Unani manufacturer.

The Delhi Administration has an intelligence cell which is functioning for the last 3 years. Difficulty in enlisting support from Police particularly during night hours is the main handicap in carrying out raids against offenders. During 1975, 148 raids were carried out. 42 of these raids proved successful. As regards offences under the Drugs and Cosmetics Act & Rules thereunder, 24 cases were decided in the court in which punishment varying from 3 months to 4 years imprisonment besides fines was imposed.

No shortage of drugs has been noticed in Delhi. Abuse of psychotropic substances has also been controlled.

A survey on the prevalence of spurious drugs was carried out employing volunteers. 305 samples were drawn and tested but no sample was reported as spurious.

Dr. Sharma commended the services rendered by the Assistant Drugs Controller (India), North Zone, Ghaziabad and his inspectorate in carrying out joint inspections, organizing the North Zone Drug Controllers conference, taking part in surveys on the incidence of spurious drugs and carrying out raids with his officers. He thanked the

Central Government for providing financial assistance to augment testing facilities in Delhi.

ASSAM

Dr. Banerjee stated that in Assam, the Director of Health Services is the Drugs Controller who is assisted by an Asstt. Drugs Controller and four inspectors of whom only three are now in position.

Control over the manufacture of homoeopathic medicines is being exercised but there is no control yet over Ayurvedic & Unani medicines. Drug Control Administration in Assam has a cell for launching prosecutions. Instructions have been issued to the wholesalers that they should get certificates from manufacturers certifying that medicines supplied are in good condition. He mentioned that certain firms in Assam have run into difficulties for importing pethidine without an I.T.C. licence.

Dr. Banerjee stated that a scheme for establishment of an independent Drugs Control Laboratory in the State is under consideration of Assam Government. He desired that a copy of the Blue Print prepared by the Government of India in respect of the Building Plan for a combined Food and Drug Testing Laboratory may be furnished to him for guidance.

As regards the existing testing facilities, he stated that his state is utilizing the facilities available with the Central Drugs Laboratory, Calcutta & the Drug Testing Laboratories in Baroda and Bangalore.

Summing up the general discussions, the Chairman stated that

(1) while there appears to be an all round tightening up of quality control over drugs in the country, it was surprising that the results of tests reports received indicate that the number of sub-standard drugs has gone up to the extent of 20 to 25%. To say that most of the samples have been failed for trivial reasons like colour etc is not going to convince the Government or the legislature. He suggested that statistics should be compiled in regard to the number of samples tested during 1974-75 and the number reported to be not of standard quality and the reasons for declaring the samples as substandard analysed with a view to finding out as to how many of these samples have been found to be sub-standard on account of minor deficiencies such as non-uniformity in weight, chipping of tablets, dis-colouration and how many of these have been found to be deficient in the content of active ingredients. It will then be possible to identify the factors which were responsible for the increasing reports of sub-standard drugs.

(2) The Chairman stated that the Government of India had recently appointed an Expert Committee to examine the conditions of manufacture and scope for expansion of production of vaccines and sera in various institutions in the country. A team of experts visited various institutions and furnished their report to Government. The report has brought out glaring deficiencies and alarming conditions of manufacture in many of these

institutions. In respect of vaccine institutes, the committee has recommended that Central Government should appoint a panel of experts to inspect and improve their manufacturing and testing facilities and conditions prevailing therein. The State Governments will be informed of the recommendations of the Committee for necessary action.

(3) The Chairman again requested the members to expedite the results of survey on the extent of prevalence of spurious drugs.

The Annual reviews of the activities of the State Drugs Standard Control Organisation and those of the Zonal and Port officers of the Central Drugs Standard Control Organisation were circulated for the information of the members. The Government of India, Ministry of Health & F.P. Notification No. X.19013/1/72-D&MS dated 26th March, 1976 reconstituting the Drugs Consultative Committee with Drugs Controller (India) as the Chairman and Drugs Control authorities in States as members (by designation) was also circulated for information of members.

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 recommendation made by the Committee at its last meeting.

Appendix –I to the Agenda :

Item 3 : Use of second hand bottles for filling transfusion solutions.

The decision taken at the last meeting of the Drugs Consultative Committee that the use of second hand bottles may be permitted for manufacture of transfusion solutions provided that the manufacturers use their own bottles and take responsibility for ensuring absence of particulate matter in their product was reviewed. After some discussion it use decided that the status quo may be maintained.

Item 13 : Lifting of Narcotics drugs.

The Deputy Narcotics Commissioner, Gazipur factory was requested earlier to furnish to the State Drug Control Authorities information regarding lifting of Narcotics drugs on a quarterly basis to enable State Drugs Controllers to ensure that the quantities allotted to the manufacturers are lifted by them. The State Drugs Controllers, however, informed that quarterly statements have not been received from the

Narcotics Commissioner. The Chairman promised to write to the Narcotics Commissioner again in the matter.

(15) **Qualifications of Inspectors – Requirement of 3 years' experience in the manufacture and testing of drugs listed in Schedule C – Amendment to Rule 49.**

It was agreed that the draft amendment proposed by S/Shri M. R. Shastri and M. K. Rangnekar to the Firs t and Fifth proviso to Rule 49 should be accepted and these draft amendments referred to the Drugs Technical Advisory Board for its approval.

Item No.3 : Question arising out of the minutes of the last meeting of the Drugs Consultative Committee.

3(a) **Consideration of the recommendation of the sub-committee regarding upward revision of fees for various licences under the Drugs and Cosmetics Rules.**

The Chairman explained to the members that at the last meeting, a sub-committee had been constituted to go into the question of the revision of various licences for manufacture, sale, inspection etc. and the recommendations made by the **Sub-Committee** required to be considered. The members felt that the fees recommended by the Sub-Committee were quite low. Besides, no uniform yard stick appeared to have been used in scaling up the fees.

After discussions, it was agreed that the licence fees for various licences should be scaled up uniformly and that the following yard-stick should be adopted :

1. For grant of original licnece – 200 % of the existing fee.

2. For renewal of the original licence – 200% of the existing fee.

3. Late fees for grant or renewal of licence – 180% of the existing fee.

4. For issue of a duplicate copy of a licence – 125% of the existing fee.

5. Inspection fee for grant of a licence in the first instance – 200% of the existing fee.

6. Inspection fee for renewal of a licence – 200% of the existing fee.

7. Inclusion of additional items in the licence – Rs.50 per item.

It was also agreed that there should be an inspection fee for the grant of a loan licence and it should also be governed by the above yard stick.

The Committee also recommended that in Form 25 relating to licence to manufacture for sale of drugs other than those specified in Schedule C and C(1), the words "categories of drugs" occurring therein should be changed to read as "items of drugs".

3(b) **Proposal to amend the Drugs and Cosmetics Rules to lay down the procedure for disposal of drugs in the event of cancellation of licence.**

A new draft Rule 66-A to the Drugs and Cosmetics Rules requiring a dealer to dispose of drugs in stock with him to a licensed dealer in the event of cancellation of his licence for sale of such drugs, had earlier been circulated to members inviting their views on it.

The Committee considered the views of the members as given in **Appendix IV** to the Agenda and agreed to the draft Rule 66-A being incorporated in the Drugs and Cosmetics Rules.

Item No.4 : Classification of Ophthalmic preparations.

The Chairman explained that ophthalmic preparations have to be sterile. The conditions of their manufacture are the same as those for injectible preparations. The point to be considered, therefore, was whether ophthalmic preparations should be classified in Schedule C of the Drugs and Cosmetics Rules. If, however, it is decided to classify them under item 12 of Schedule C, the question as to what repercussions that such a decision will have on the classification of other sterile preparations such as 'Sterile Absorbent Cotton' will also have to be considered.

It was agreed that a separate entry to cover ophthalmic preparations should be incorporated in Schedule C.

Item No.5 : Proposal that a PROFORMA should be laid down to contain vital information on adverse reactions resulting from the administration of certain Drugs so as to facilitate follow up action.

The Committee approved the profoma as proposed by the Deputy Drugs Controller (India), West Zone, Bombay for eliciting discreet information by the Inspectors of State Drugs Control Administration in the case reports of adverse reactions with certain drugs and for furnishing it to the Zonal Officers concerned for prompt investigation and follow up action with the

Drug Control authorities of the States where the manufacturers are located. The proforma as approved by the Committee is **attached**.

Item No.6 : Payment of fees for grant or renewal of licences for manufacture or sale of drugs under the Drugs and Cosmetics Rules, 1945 – Laying down time limit for refund of fees.

It was explained to the members that the opinion of the Law Ministry was that the fees accompanying applications for grant or renewal of licences are liable to be refunded in the event of the licences applied for not being granted. The question at issue is whether any rule should be made under the Drugs and Cosmetics Rules, laying down the time limit for making applications for refund of fees in such cases.

The members felt that if such a rule is made, applications for refund of fees will be received in all cases of rejection of applications for grant or renewal of licence and it will cause administrative difficulties for the licensing authorities.

After discussions, it was agreed that the status quo should be maintained and the States may act as they deem fit in regard to refund of licence fees.

Item No.7 : Provision for endorsing names of drugs in Homoeopathic Manufacturing Licence.

It was agreed that a list giving the names of drugs permitted to be manufactured should be enclosed with the licence granted for manufacture of homoeopathic medicines.

Item No.8 : Relabelling of products whose labels get damaged during transit.

The Chairman explained that labels of products dispatched by manufacturers to out-stations sometimes get damaged during transit. At present, they are required to recall the goods for relabelling, considering the genuine difficulty faced by the manufacturers in this regard, the committee should decide on a uniform procedure to be adopted in such cases.

After discussion, it was agreed that Relabelling / Redressing of products damaged during transit should be permitted to be carried out at the premises of the manufacturers own sales depots or branch offices. The redressing should be done with the permission of the State Drug Control authorities concerned and in the presence of a Drug Inspector. Proper records of all drugs so redressed should also be required to be maintained. However, in cases where such sales depots or branch offices of the

manufacturers do not exist, the drugs should be sent back to the manufacturer for redressing.

Item No.9 : Sale of drugs in running trains.

The Chairman stated that the Railways are very keen to stock & sell drugs from the dining cars of running trains for meeting the requirements of passengers during an emergency. The question to be considered is whether railways may be exempted from stocking household remedies or they should be covered by a sale licence. In the latter case, who should be the authority for granting the licence particularly as the trains pass through a number of States.

The consensus view of the committee was that trains as well as coastal ships should be exempted under Schedule K of the Drugs & Cosmetics Rules from the requirement of obtaining a sale licence for stocking & selling household remedies and necessary provision to this effect should be made.

Item No.10 : Withdrawal of Transfusion solutions showing presence of fungus growth.

The Committee decided that the present procedure that a manufacturer should withdraw the entire stock of a batch from the market even if only a few bottles of a batch show the presence of fungus growth should continue to be followed. The licensing authority must ensure that the batch is withdrawn by the manufacturer.

The clear bottles should be segregated from the stocks withdrawn and representative samples should be tested for sterility in the quantities required. If the samples tested are found to be sterile, the bottles which are free from fungus growth may be allowed to be released for sale in the market. On the other hand, if the sample fails in sterility, the entire batch should be got destroyed.

The above procedure should be followed only in cases where only a few bottles in a batch show fungus growth and where it is suspected that the fungus growth may be due to cracks in bottle developed during transit.

Item No.11 : To review the exiting procedure of recall by manufacturers of drugs found deficient.

The Chairman stated that when a drug is found deficient and is required to be withdrawn from the market, the instructions sent to manufacturers in this regard in many cases are not carried out with the result that the stocks of the defective drugs continue to move in the market. He desired that the

procedure followed should be such as would not leave the withdrawals to manufacturers alone. The licensing authorities should make sure through the agency of Drug Inspectors that actual withdrawal take place.

This view was supported by Dr. Gujral who stated that a drug found to contain phenol in Aug.74 and required to be withdrawn from the market by the manufacturers, was found to be moving in Rajasthan even after 1 ½ years later. This points out the need for a proper procedure to be evolved for ensuring withdrawal of defective drugs.

After discussion, the committee agreed to the following procedure being adopted uniformly by the State Drugs Control Authorities :-

The Drugs Controller of the State where the manufacturer is located will ascertain from the manufacturer particulars regarding the areas to which and the names & addresses of the distributors to whom, the drug has been supplied. He would inform these particulars to the Drugs Controller of the State(s) to which the stocks of defective drugs were supplied by the manufacturers and the latter would ensure that the stocks of the drugs complained of are withdrawn by the manufacturer. The dealers could be told in writing about the bad quality of the drug and about the need for return of the stocks to the manufacturers. The Drugs Controller of the State, where the manufacturer is located, would also direct the firm to recall the stocks from the market and destroy them in the presence of his State Drugs Inspector, as at present.

Item No.12 : Proposal for furnishing the State Drug Controllers with the names of distributors to whom drugs, which have caused untoward reaction to patients, had been supplied after obtaining the information from the manufacturers.

The Deputy Drugs Controller (India), West Zone, Bombay stated that some of the States like Madhya Pradesh do not have a full complement of Drug Inspectors. When drugs causing untoward reactions are reported to them as moving in their State, it becomes difficult for their inspectors to tour all the districts under their charge for checking the movement of such drugs. It was suggested that if the names of distributors in their State to whom the supply was made by the manufacturer was made available the sale of defective drugs could be suspended at all levels of sale and prompt action would be possible in the matter.

It was agreed that the Drugs Controller of the State, where the manufacturer is located, should ascertain the particulars of the distributors to whom the drug was supplied and inform the Zonal Officer or the State Drugs Controllers concerned for further necessary action.

Item No.13 : Suggestion to have a uniform list of drugs which are permitted to be sold by petrol pumps in Form 20-A of the Drugs and Cosmetics Rules.

It was agreed that the drugs that are permitted for sale through petrol pumps should be only simple household remedies which are not included in Schedule E, G, H and L of the Drugs and Cosmetics Rules and sale which do not deteriorate on storage. Thus analgesic tablets, Laxatives, cough-syrups, cough tablets, antacids, anti-septics, pain balms, gripe water and items given under item 13 of Schedule K of the Drugs and Cosmetics Rules could be permitted to be sold by the petrol pumps against restricted licences for retail sale in Form-20A.

Certain States have prepared list of drugs which can be licenced for sale under the restricted licence for retail sale and such lists could be followed for granting retail licence to petrol pumps also.

Item No.14 : Proposal for making a suitable provision in the Drugs and Cosmetics Rules empowering the licensing authority to refuse to grant a sale licence if the firm is not prepared to keep the shop open after normal working hours.

The Committee felt that it may be legally difficult to provide for refusal to grant a sale licence to a firm which is not prepared to keep the shop open after normal working hours. There may be factors such as less turnover of sales during the night, extra cost involved in keeping registered pharmacists for disponsing prescriptions during the night, problem of pilferage of drugs, security risks etc. which may make a person reluctant to keep his shop open after normal working hours. In cities like Delhi, Calcutta etc. co-operation of chemist, hospitals and Super Bazar have been enlisted to keep the shops open after normal working hours at least by rotation or by turns. Rather than making it a law, it would be better to provide some incentives to the chemists for rendering service at night. This aspect may be pursued with the Ministry of Chemicals and Fertilisers who administer the Drugs (Price Control) Order, 1970.

It was also agreed that the opinion of the Ministry of Law and Justice should be ascertained on whether the Drugs and Cosmetics Rules can be amended to empower the licensing authority to refuse to grant a sale licence if the firm is not prepared to keep the shop open after normal working hours.

Item No.15 : Suggestion that list of items that may be allowed to be repacked should be enlarged.

The Committee decided at its last meeting that the list of 65 items recommended for being permitted to be repacked by the **Sub-Committee**

set up for the purpose is for the guidance of the members. This list should not normally be enlarged. In case, however, a firm intends to repack a particular item not covered by the list for meeting a specific order from D.G.S. & D, Railways or any other Central or State Government Department, he could be licensed to repack that particular item. This should, however, be an exception.

Item No.16 : Consideration of the question whether the wholesalers / distributors and stockist could over stamp the revised price of a product on the label or container in indelible ink on behalf of a manufacturer.

It was clarified that under the Drugs (Price Control) Order, 1970 it is the legal responsibility of every manufacturer, importer or distributor to display in indelible print mark on the label of the container of the formulation, the maximum retail price of that formulation. So long as the prices are corrected by a manufacturer, importer or distributor, no matter how they do it, whether by recalling the stocks or formulations already sold to dealers / retailers etc. or by deputing their representatives, the legal requirements would seem to have been met. With the field staff available with the manufacturer, distributors etc., it would not be difficult for them to correct the prices by deputing their representatives for the purpose.

Item No.17 : Consideration of action that should be taken against the manufacturers when a product manufactured by him is declared as not of standard quality by Government Analyst but the control samples with manufacturer is claimed to be of standard quality.

The Committee felt that the control sample is likely to be substituted and cannot be relied upon. The manufacturer should be asked to withdraw the entire batch found to be not of standard quality and dispose it of as per the procedure already agreed upon **vide item 11**. Instead of referring to the control sample kept by the manufacturer, the licensing authority could try to draw a sample belonging to this batch from a sale premises and test it if considered necessary.

Item No.18 : Amendment of Rule 121-A relating to test for Pyrogens.

It was pointed out to the Committee that the present Rule 121-A of the Drugs and cosmetics Rules excludes parenteral preparations below 10 ml. from pyrogen test whereas Indian Pharmacopoeia requires that all parenteral preparations intended for intravenous administration should be free from pyrogens. It was, therefore, suggested that Drugs and Cosmetics Rules should be brought in time with the I.P. requirements.

The Committee desired that the Drugs Control authorities of West Bengal and Maharashtra should go through the provisions / practices being

followed in other countries in this regard and report their finding to the Committee. A decision in the matter could be taken after the proceedings / practice followed in other countries are known.

Item No.19 : Amendment of Rule 158-A relating to conditions of licence to manufacture for sale Ayurvedic (licensing Siddha) or Unani drugs.

The Committee felt that it would be premature to provide for maintenance of an Inspection Book for licensees manufacturing for sale Ayurvedic (including Siddha) or Unani medicines.

Item No.20 : Uniformity of action regarding drugs declared to be not of standard quality because of minor defects.

It was brought to the notice of the committee that a large number of drugs are reported as not of standard quality by Government Analysts on account of minor defects such as chipping of tablets, discoloration of coating, mottled appearance, non-uniformity of weight, presence of particulate matter etc. though these drugs are otherwise all right and especially as regards content of active ingredients. As these sub-standard reports generate adverse public reaction and give a distorted impression of the quality of drugs manufactured in the country, the term "Not of Standard Quality" should be appropriately defined.

It was explained that there is no specific definition for sub-standard drugs and sub-standard drugs are those which do not conform to the prescribed standards of quality. The various points made by the members were as under :-

(1) Even though guide lines exist for examination of transfusion solutions for particulate matter is by visual examination with unaided eye against natural day light, certain samples are declared to be of sub-standard quality due to presence of particulate matter in one State while they are passed by Government analysts of other State.

(2) Proprietary preparations have been, in most cases, declared as not of standard quality on the basis of description although description is not a standard for proprietary medicines under the Rules.

(3) The main purpose of analysts' should be to analyse drug samples and find out something which one cannot find out otherwise. The analyst should give the results of tests and not the opinion.

(4) While the Government analyst should exercise his discretion judiciously there should be a uniform procedure for declaring drugs as

not of standard quality on minor defects, as also the uniformity of action on the reports.

(5) The capacity for testing drug samples for States at the Central Drugs Laboratory is very limited. In the next few years, more laboratories will have to be developed in States. As the Central Government is extending financial assistance to States for the purpose, the number of laboratories will increase. Thus lack of availability of trained analytical personnel would be felt. This should be kept in view now.

Summing up the discussions on the subject, the Chairman asked the members to send details regarding the number of samples tested during last year in their respective States, the number of samples found to be of standard quality and the number of samples found to be not of standard quality on various courts separately for (1) minor defects such as, chipping of tablets, broken edges, presence of particulate matter, description and (2) serious defects such as deficiency in content of active ingredient, non-sterility, presence of pyrogens etc. This was agreed to by the members.

It was also agreed that an Analysts conference should be convened at Calcutta to which all Government Analysts, the Director, Central Drugs Laboratory and the Central & State Drugs Control Authorities should be invited and at this conference the above problem should be discussed amongst others so as to evolve a common approach to the problem.

The Chairman stated that especially in view of the financial assistance now being given by the Central Government for setting up combined Food and Drug Testing Laboratories or for augmenting the existing facilities for testing, a large number of laboratories will start functioning in the country in the next few years. It is, therefore, necessary that the question of training an adequate number of analysts for manning these laboratories should be considered from now on. He, therefore, suggested that the training programme for analysts should be conducted by Karnataka, Maharashtra and Gujarat in their State Laboratories. He requested the members from these States to prepare detailed Schedule of training, indicating the areas of training, the number of persons that could be trained & the duration of training as well as the number of courses of training that could be held in a year. They **agreed** to supply this information.

Item No.21 : Amendment of Rule 65(4) (4) of Drugs and Cosmetics Rules relating to Records of Purchase of drugs by the dealers.

The Committee agreed that Rule 65(4) (4) should be amended to include a provision for maintenance of purchase vouchers of drugs stocked by a

licensee as records of purchase, in addition to the register maintained by him.

Item No.22 : Exemption from Central Excise Duty of Capsules printed with the name of the manufacturer.

The Drugs Controller, Delhi Administration stated that manufacturers in Delhi had represented that capsules of pharmacopoeial drugs printed with their name are considered as proprietary medicines for the purpose of levy of Central Excise duty.

The Committee felt that such printing was perhaps considered by the Excise authorities as distinctive labeling linking the product with the manufacturer. Certain members, however, stated that the problem might be specific to Delhi as manufacturers in other States have not so far complained of it.

It was agreed that the question should be **taken up** with the Excise authorities by the Delhi Drugs Control Administration.

Item No.23 : Allocation of raw-materials vis-a-vis recommendations made by the Drugs Control Authorities in favour of manufacturers.

The item came up for discussion when the representatives of the Ministry of Chemicals & Fertilizers, the S.T.C. and the I.D.P.L. were present.

Shri Kumar, of I.D.P.L., clarified that the Union Ministry of Chemicals and Fertilizers had issued instructions earlier according to which norms have been laid down to allocate certain fixed quantities of canalized drugs to new units in the first instance. Once these fixed quantities are utilized by the units and the State Drugs Controller certified that the party has utilized the initial allocation, the same quantum of raw material can be allocated once more in the same year in favour of the party.

Item No.24 : Prohibition against altering inscriptions on containers labels or wrappers of drugs.

The Committee agreed that Rule 110-A which prohibits altering of inscriptions on containers, labels or wrapper of drugs applies to Schedule C and C(1) drugs only. It felt that this rule should be made applicable to all drugs.

Item No.25 : Inclusion of a rule in the Drugs and Cosmetics Rules to provide for confiscation of Cosmetics similar to rule 58 and 58-A.

The Chairman informed the Committee that a draft amendment in this regard is already **under consideration** of the Government.

Item No.26 : Import Trade Control Order.

Shri Narasimhan desired that the Committee should lay down guidelines to facilitate the licensing authorities to allow transfer of imported raw materials from one actual user to another under para 94(1) and 94(2) of the Import Trade Control Order.

The Committee felt that no guidelines are necessary in this regard as it is compulsory on the part of the State Drugs Controller to allow transfer of raw materials. However, transfers should be permitted only as an exception and not as a general routine. Further, it would be preferable to transfer the materials to a public sector or a joint sector undertaking, wherever possible.

Item No.27 : Definition of bulk drug under the Drugs (Price Control) Order to be elaborated.

Shri Shanbhogue desired that the definition of bulk drug under the Drugs (Price Control) Order may be enlarged so as to include pharmacopoeial preparations like liquid paraffin, boric acid, sod. salicylate etc. repacked in similar packings for use by consumers.

The Chairman informed the Committee that the issue was raised earlier by other State Drugs Controllers also and the Ministry of Chemicals and Fertilizers were requested to issue necessary instructions in the matter. As the decision of the Ministry had not been received so far, he requested Shri Keayla, Deputy Secretary to the Government of India, Ministry of Chemicals & Fertilizers, who was present at the meeting, to look into the matter personally and **expedite** their decision.

Item No.28 : Consideration of the question whether the licensing authority should refuse the grant of a licence in the name of a new firm proposed to be started by a person whose licence has been cancelled or by his close relatives.

As the State Drugs Controller Chandigarh who had proposed the item for discussion was not present at the meeting, the item could not be discussed.

Item No.29 : Proposal that M.B.B.S. degree holders should be considered as qualified person under Rule 65(15) (ii) of the Drugs and Cosmetics Rules.

The Drugs Controller, Haryana desired that M.B.B.S. degree holders should be considered as qualified persons under Rule 65(15) (c) of the Drugs and Cosmetics Rules. His views was that when a Registered Medical Practitioner can dispense medicines to his own patients under the Rules, it would be discriminatory if he is denied to render this service to other patients.

Shri Rangnekar stated that a provision should be made in the Drugs and Cosmetics Rules permitting the Licensing Authority to approve person having a knowledge of pharmacy and practical experience of dispensing which is considered adequate as 'qualified person' for purpose of dispensing of medicines only. Such person should not be permitted to compound medicines which should be left to the registered pharmacist. In his view such a provision would be helpful in making an increased number of qualified persons available for dispensing services in remote areas and villages. This view was supported by the Drugs Controller, Rajasthan and Haryana. It was also mentioned that because of the existing definition of 'qualified person' under the Rule, the dealers who are not able to keep a registered pharmacist were going in for wholesale licences but in actual practice they indulged in retail business.

Shri Shanbhogue stated that Rule 65(15) (c) was amended to give protection to academically unqualified persons who were already doing the job of dispensing and compounding and had the necessary experience as on 31st December, 1969. If a new category of persons was introduced into the profession again, the future prospects of Registered Pharmacists would be affected adversely. Besides, half lacked and half trained persons would harm the interests of the consumers and of the profession of pharmacy besides creating unemployment among pharmacists. He was strongly opposed to the idea of having a second category of qualified persons. He was supported by Shri Shastri of Gujarat and Shri Narasimhan of Tamil Nadu. Shri Narasimhan stated that it was only the dealer who was clamouring for a cheap substitute for Registered Pharmacists.

The Chairman stated that there were divergent views on the subject. While one section wanted relaxation of the rule, the other did not. There was a third point of view also, that the medical practitioners should be recognized. It would be difficult to reconcile these views. At present persons approved upto 31st December, 1969 would be deemed to be qualified persons and in the Pharmacy (Amendment)Bill a provision is being made for these persons to be registered. Further, in the Amendment Bill it has also been provided that five years from the date of passing of this Bill, Section 42 of the Pharmacy Act will come into force in the States which have not issued the notification under Section 42 and no body except registered pharmacists would be allowed to run the

pharmacies. In view of this it would be difficult to consider making any provision which would run counter to the provision of the Pharmacy (Amendment) Bill.

Item No.30 : Definition of Registered Medical Practitioners – Amendment of Rule 2 (ee) (ii).

As the Drugs Controller, Jammu & Kashmir, who had suggested this item, did not attend the meeting, the item was not taken up for consideration.

Item No.31 : Consideration of the question of declaring drug samples as not of standard quality by Govt. Analyst if they are found as misbranded and or adulterated under the provisions of Section 17(e) and Section 17B(a), 17B(c), 17B(d), 17B(e) and accordingly amending the Schedule II of the Drugs and Cosmetics Act.

The Chairman stated that in the Drugs and Cosmetics Amendment Bill which is being introduced in Parliament the definition of the term 'adulterated' drug has been enlarged to include drugs containing toxic materials and this would meet the difficulty of Analysts as pointed out by Shri M. R. Shastri.

Item No.32 : Proposal that Rule 69-A and 76-A should be amended on the lines of Rule 62-A for laying down guidelines for issuing loan licencees.

The Chairman stated that in certain States loan licences under the Drugs and Cosmetics Rules were being issued on firms which did not have facilities of their own for testing the raw materials and the finished formulations. This practice should not be allowed in principle, as such manufacturers who do not have the necessary infrastructure for Quality Control may not be able to exercise the required control on the quality of the products manufactured by them on behalf of the loan licences.

The Committee agreed that in granting loan licences, it should be ensured by the licensing authority that the firm, whose manufacturing facilities are availed of, should possess necessary facilities for testing raw materials and finished formulations manufactured by them. The intention was that a person, whose facilities are being used, should not himself be utilizing some body else's facility for testing. No amendment in the rules was, however, considered necessary.

Item No.33 : Standards for drugs to be exported.

Shri Chandrasekharan Nair pointed out that the Second Schedule to the Drugs and Cosmetics Act does not mention any standards for export and

desired to know if a firm can be permitted to manufacture drugs included in IP as conforming to BP, USP or BPC Standards for purposes of export.

The Committee agreed that drugs meant for export could be allowed to be manufactured in accordance with any pharmacopoeial standard as required by the importing country.

Item No.34 : Standards for patent and proprietary medicines.

Dr. Gujral pointed out that additional standards have not been prescribed for patent and proprietary medicines, as provided for in the Second Schedule to the Act.

The Chairman informed Shri Gujral that additional standards are **being** laid down.

Item No.35 : Qualification of Analytical Chemists.

It was agreed that specific qualifications should be laid down in Rule 71(4) and other corresponding Rules for analytical chemists employed by manufacturers of drugs. The basic qualifications should be degree in Chemistry, Pharmacy, Analytical Chemistry, Microbiology or Medicine with experience in the analysis and testing of drugs which should be adequate in the opinion of the licensing authority.

Item No.36 : Restriction on the number of formulations.

Dr. Gujral desired that some restriction should be placed in the additional items being included on the manufacturing licence. At present there is no restriction and the manufacturers have long lists of additional items endorsed on the licences on payment of fees, even if most of such items are not being manufactured. The endorsements only help the firms to quote for rate enquiries against indents. It was suggested that the licensee might be asked to surrender an equal number of items from the licence when he asked for endorsement of additional items.

The Committee felt that legally a firm cannot be asked to surrender any items from his licence. However, when the licence fee is raised as agreed to under item No.3, and fee is charged for every additional item, it may serve as a deterrent to firms.

Item No.37 : Preparation of standard plans, blue prints and guidelines for drug manufacturing units.

Shri Gujral desired that for guidance of the licensing authorities as well as prospective enterpreneurs, standard plans and blue prints of the building

for manufacture of different categories of drugs and suitable guidelines for the information of drug manufacturing units should be prepared.

It was agreed that a sub committee consisting of the following members should draw up standard plans, guidelines etc. for use of new units / drug control authorites :-

1.	Shri M. K. Rangnekar, Commissioner, Food and Drug Administration, Maharashtra State, Bombay	Chairman
2.	Dr. A. C. Kar, Director, Drugs Control, West Bengal.	Member
3.	Shri. M. R. Shastri, Director Drugs Control Admn., Gujarat	Member
4.	Shri K. N. Shanbhogue, Drugs Controller, Karnataka	Member
5.	Dr. D. Costa Frias, Drugs Controller, Goa	Member
6.	Dr. J. L. Kaul, Asstt. Drugs Controller, India North Zone, Ghaziabad.	Member Secretary

The Committee should draw up standard building plans for manufacture of different categories of drugs including laboratory facilities showing the layout, design, minimum area, provision for the type of equipment their cost and the sources of their supply, the placement of equipment, service lines etc. on the lines of a project report. The report should be furnished within **six months** by the sub-committee.

Item No.38 : Proposal that sale of ACD Bottles should be restricted only to licensed blood banks so as to reduce malpractices in manufacture / collection and sale of blood by unauthorized persons.

The Committee felt that manufacturers of ACD Bottles should be asked to supply these bottles only to licensed Blood Banks. The U.P. State Drug Control Authority should furnish particulars of ACD bottle manufacturers whose bottles are being supplied to parties other than the licensed blood banks in the State to the Drug Controllers of the concerned States where

they are located so that suitable directions may be issued by the latter in this regard.

Item No.39 : Consideration of the policy that should be adopted in case of licensees who do not apply for the renewal of their licensees within grace period of six months by paying penalty, but submit the application after the grace period is over.

The Chairman clarified that a new rule in the Drugs and Cosmetics Rules has been introduced which provides for imposition of penalty each month upto six months besides the licence fee, if a person fails to renew his licence. If the licence is not renewed within the prescribed time of six months and the licensee still carries on his business he can be proceeded against legally. No amendment of the rule is, therefore, necessary.

Item No.40 : Consideration of the question of using polythene or P.V.C. containers for packing of drugs containing solvents like chloroform.

The Chairman reiterated its earlier decision taken at the 15th meeting held in New Delhi on the 9ths and 10th March, 1972, an extract of which relating to packing of liquid orals in plastic containers is reproduced below :-

"It would not be desirable to grant permission to pack liquid oral preparations in polyethylene containers irrespective of the density of the material used for fabrication of the containers as contained in the directive issued by the Commissioner, Food and Drug Administration, Maharashtra State."

Item No.41 : Proposal that Rule 106-A of Drugs and Cosmetics Rules, 1945 should be amended so as to include combinations homoeopathic medicines.

The Drug Control authorities in Maharashtra State desired that Rule 106-A should be amended so as to require that the name of the combination homoeopathic medicine should be indicated on the label. The present rule applies to only single ingredient homoeopathic medicines.

The item came up for discussion when the Adviser in homoeopathy in the Department of Health was present. Adviser in homoeopathy was of the view that only the composition of the "combination homoeopathic preparation" need be given.

The Committee agreed that only the proprietary name and the composition of the drug should be given on the label in the case of combination homoeopathic preparations.

Item No.42 : **Consideration of the question as to whether packing of drugs meant for pediatric use should be restricted only to consumer packing.**

The Committee was unanimously of the view that drugs meant for pediatric use should be allowed to be marketed only in consumer packing. Marketing of such drugs in bulk packing should be discontinued.

Item No.43 : **Any other Item with the permission of Chairman**

(a) **Consideration of the question whether medicinal gases could be exempted from clause (1) of Rule 74 which lays down that reference samples have to be kept for a period of three years.**

The Committee agreed that in the case of medicinal gases for requirement of maintenance of reference samples is not practicable and need not be insisted upon.

(b) **Labelling with standard of a drug included in an edition of a pharmacopoeia earlier to that immediately preceding the current edition.**

The Chairman stated that if a drug which is not included either in the current edition of a pharmacopoeia or in edition immediately preceding it but only in an edition earlier to the latter is labeled with "the standard" referring to that edition of the pharmacopoeia, for instance, if Sulphasomidine Tablets are labeled as 'B.P.63', no objection need be taken to such labeling. It is better that such drugs are labeled with a standard instead of none, although this cannot be insisted upon legally. The Committee agreed with this view.

(c) **Consideration of the question of permitting the manufacture of cosmetic "Dental Tooth Paste" containing 50% Tobacco powder.**

Shri Shastri stated that an application from a firm for manufcture of toothpaste containing 50% Tobacco powder was not considered by his Administration, as two cancer institutes consulted in the matter were of the opinion that such a tooth paste is likely to be carcinogenic. But the firm had represented that such toothpastes are allowed to be marketed in other States viz. Orissa, Punjab & Maharashtra. Shri Rangnekar informed that Tooth paste containing 10% burnt tobacco powder is permitted manufacture in his State.

The Chairman stated that S/Shri Shastri and Rangnekar may **forward** the view of their experts in the matter to him so that they could be considered and necessary decision taken on this issue.

(d) **Disposal of drugs like physicians samples found in stock with licensees.**

Shri G. Rama Rao of Andhra Pradesh stated that when stocks of drugs like physicians samples are found with licensees, the licensing authority suspends the licence or takes departmental action but the law is silent as to what should be done with the stocks of such drugs. He desired to have the guidance of the Committee in the matter.

The Chairman clarified that the stock of such drugs should not be allowed to be sold. If the stocks are good, these could be given for use in a Government hospital or else destroyed.

(e) **Ban on the manufacture of Penicillin Ophthalmic Ointment.**

Shri Rangnekar pointed out that after imposing a ban on the manufacture of Peniclin Skin Ointment, there has been a spurt in the manufacture of Penicillin Eye Ointment. As it was likely that Penicillin eye ointment was being used as skin ointment, he desired to know if the manufacture of the former could also be banned.

The Chairman stated that Penicillin Eye Ointment has been considered "essential" by the Essential Drug Committee and it may be difficult to ban its use.

(f) **Adulterated and Misbranded Ayurvedic (Including Siddha) and Unani Drugs.**

Shri Rangnekar stated that it is necessary that a provision should be made in the Drugs and Cosmetics Rules for control over manufacture of adulterated and misbranded Ayurvedic (including Siddha) and Unani drugs.

The Chairman stated that in the Drug Amendment Bill now under consideration a new definition is being introduced for exercising control over adulterated and misbranded Ayurvedic / Unani drugs.

(g) **Loan licences – provision should be made for the manufacture of Ayurvedic Medicines.**

It was proposed that a provision for the grant of loan licences for the manufacture of Ayurvedic Medicines should be made in part XVI of the Drugs and Cosmetics Rules. The Committee was of the view that loan licensing of manufacture of Ayurvedic drugs was not necessary.

(h) **Provision of a approval of laboratories for test or analysis of Ayurvedic (including Siddha & Unani) raw materials and finished products.**

It was pointed out that there is no provision in the rules to accord approval to Laboratories for Test or Analysis of Ayurvedic including Siddha and Unani raw materials and finished products. The laboratories approved for testing of Allopathic drugs may be recognized for the purpose.

(i) **Provision for Loan Licence for homoeopathic medicinces.**

It was pointed out that majority of homoeopathic manufacturers are in the small scale sector who are not in a position to comply with the Rules relating to premises, staff and equipment. It was, therefore, proposed that a provision should be made for grant of loan licences for manufacture of homoeopathic medicines.

The Committee did not consider it necessary to allow manufacture of homoeopathic medicines on loan licences.

*(j) **Restrictions on multiple-dose packing of Injections.**

It was decided that multiple-dose packing of injections can be permitted up to 30 ml. The number of withdrawals of the drug from the vial should, however, be restricted to 10 as it was felt that Butyl rubber plugs used for capping vials would not be able to bear more than 10 pricks. It was further agreed that the same practice should be followed uniformly in all the States.

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

corrigendum inserted vide letter no. X-19013/4/76-D dated Nil.