MINUTES OF THE 21ST MEETING OF THE DRUGS CONSULTATIVE COMMITTEE HELD AT NEW DELHI ON THE 8th & 9TH NOVEMBER, 1979

The Chairman welcomed the members to the 21st meeting of the Drugs Consultative Committee. He stated that three member of the committee namely Shri K. N. Shanbhogue, Drugs Controller Karnataka, Shri B. M. Patel, Director, Drugs Control Administration Gujarat and Shri P. M. Varkey, Drugs Controller Kerala had since retired. Shri K. N. Shanbhogue was a member of the committee for 19 years and contributed substantially to the deliberations of the Committee. Both Shri Patel and Shri Varkey were with the Committee for a comparatively much shorter duration, but their contribution to the deliberations of the Committee was significant. The committee at the instance of the Chairman, placed on record its appreciation of the contributions made by these members.

The Chairman informed the members that the publication Drugs and Cosmetics Act & Rules has been brought up-to-date and 25,000 copies of it have been published. He requested them to inform manufacturers and dealers in their respective States of the availability of the up-dated publication and ask them to bring to the notice of the Drugs Controller (India) if there are any mistakes in the publication so that necessary corrections could made when the publication is reprinted.

The Chairman also informed the members that the Third Edition of the National Formulary of India had since been printed and would be released by the Press very shortly. He further informed the Committee that the Indian Pharmacopoeia Committee had been reconstituted with Dr. Nitya Nand, Director, Central Drugs Research Institute, Lucknow as its Chairman and the work on the compilation of the third edition of the Indian Pharmacopoeia had begun. The list of drugs to be included in the Indian Pharmacopoeia had been tentatively finalized. The list of drugs which are included in the Second Edition and are to be retained in the Third Edition had been circulated to All Associations of Drug Manufacturers with the request that their member firms may be asked to write to the Drugs Controller (India) if any of the monographs included in the Indian Pharmacopoeia required any change. He requested the members to advise the manufacturers to bring to his notice any errors in the existing pharmacopoeia so that these could be rectified when the pharmacopoeia is next published.

The Chairman brought the co-operation of the members in preparing the list of All India Licensed Manufacturers as on 1st January, 1980 and requested them to send 110 copies of the list of the licensed dug manufacturers in their respective States by the 30th April, 1980.

The Chairman pointed out that State Drugs Control authorities frequently ask for more quotas of narcotic drugs for their States while the existing quotas already allotted to drug manufacturers in their States had not been lifted. He advised them to evolve a

procedure whereby manufacturers in their States were required to give a quarterly return on the actual lifting of narcotic drugs and if it was observed that certain firms failed to lift the quota without valid reasons, their quota of narcotic drugs should be cancelled and considered for allotment to other applicant manufactures. This would ensure early lifting of narcotic drugs and adequate supply of such drugs.

The Chairman further said that it had come to his notice that the information furnished by the State Drugs Control authorities in respect of statistical information on the production of Psychotropic drugs is sometimes not correct. This puts the Government of India in an embarrassing position with an International body viz. International Narcotics Control Board to whom statistics regarding import and manufacture of Psychotropic substances covered by the Convention of Psychotropic Substances 1971 have to be furnished. As the information was required to be furnished in respect of only a few drugs, he requested the Drugs Controllers of States where Psychotropic drugs are basically manufactured to be very careful in furnishing statistical information on the manufacture of Psychotropic drugs, and exercise a check on the statements to ensure their correctness before they are sent to the Drugs Controller (India).

Referring to the training programme of Drug Inspectors, the Chairman informed the Committee that so far 320 Drugs Inspectors had been trained under this Scheme during the last 8 years since the Scheme was started. He stated that training of Drugs Inspectors has assumed considerable importance because of new technological developments that were taking place in the drug industry. He, therefore, requested the State Drug Controllers to take full advantage of this programme by seeing that adequate number of Drugs Inspectors from their respective States were sent for training under the programme. He said that he would welcome any suggestions for modifying this training programme so that it could be made more useful.

He also stressed on the need for timely furnishing of material for framing replies to Parliament Question or fulfilling assurances and requested the members to accord priority to this subject.

The Chairman pointed out that the pharmaceutical industry in the country was a very well established industry and India occupied the second place as a drug producing country among the developing countries. He, therefore, requested the Drugs Controllers of States to exercise more stringent control over the industry and particularly over new units by subjecting to stringent inspections either at the time of licensing on renewal. Regarding combination products the W.H.O. had ..... out criteria that should be taken into consideration before a combination product was licensed and these should constitute adequate guidelines so far as licensing of combination products are concerned. Their criteria are reproduced below :-

"Fixed – ratio combinations are only acceptable if the following criteria are met :-

1. Clinical documentation justifies the concomitant use of more than one drug;

2. The therapeutic effect is greater than the sum of the effect of each;

3. The cost of the combination product is less than the sum of the individual products;

4. Compliance is improved;

5. Sufficient drug ratios are provided to allow dosage adjustments satisfactory for the majority of the population."

The Chairman pointed out that there was a plethora of formulations specially combination products in the market and many of them are irrational. Further in many cases the manufacturers did not have methods of tests for analyzing the ingredients of the product. Positive steps were required to weed out such combinations. He suggested that Analysts must be associated in the Committees constituted in states for approval of formulations and if the applicant firms fail to furnish the methods of test and analysis, the products should not be licensed. He also referred to the following resolution passed at the Fourth Joint Conference of the Central Council of Health and the Central Family Welfare Council at its meeting held in New Delhi in January, 1978 wherein the Council had also expressed concern over the proliferation of drug products in the country:-

"The States should exercise a rigid control –

(a) at the time of grant and renewal of licence for manufacture of drugs to ensure the adequacy of facilities for manufacture and testing;

(b) during the validity period of the licence on the manufacturing operations to check that the controls exercised during and after manufacture are adequate;

(c) over the licensing of patent or proprietary allopathic medicines with a view to reducing their proliferation and;

(d) at the time of licensing of manufacture of proprietary Ayurvedic preparation to ensure that they are not marketed under names resembling those of Allopathic products;

and also take stringent action against manufacturers found manufacturing sub-standard drugs."

The Chairman further said that so far as new combinations were concerned, these could be referred to the Central Drugs Standard Control Organisation for necessary advice.

Referring to the opening remarks of the Chairman Shri R. B. Pany, Drugs Controller, Orissa desired that the Training Programme of Drugs Inspectors should be redesignated so that other Drug Control Officers could be sent for training. Speaking

about poor lifting narcotic drugs, Shri Pany pointed out that to some extent, firms in his State were handicapped due to hold up at the excise department.

The Chairman agreed that other drug control officers who wanted to get training could be accommodated in the Training Programme and the question of redesignation of the Programme would be considered. He also suggested that the State Drug Controller should take up with the Excise Authorities the question of reducing delays in the issue of excise permits.

Shri V. J. Thomas, Drugs Controller, Kerala said that there were financial constraints in sending Drugs Inspectors for training. He suggested that if the Govt. of India wrote to the State Government in this regard, it would facilitate matters. The Chairman agreed to this suggestion.

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

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

As no comments were received the minutes were confirmed.

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

The Chairman stated that the action taken on the recommendations made at the last meeting of the Committee was set out in Appendix – I and members could seek clarifications and make observations on any point given in the statement.

(3) Combined Food and Drug Laboratories.

Dr. Sane, Commissioner, Food & Drug Administration, Maharashtra, said that the scheme on combined Food and Drugs Laboratories which was a centrally sponsored scheme had been transferred to the State sector. He enquired whether this could again be brought under the centrally sponsored schemes.

The Chairman clarified that the decision to reduce the member of centrally sponsored schemes was taken by the National Development Council and this decision could not be reversed. However, he stated that as Drugs Controller (India) was require to monitor the progress of the scheme, a six monthly statement of the progress made in the ..... of Food & Drug Laboratories and in the strong thing of the testing facilities may be furnished by the State Drugs Controllers to the Drugs Controller (India). Shri Pany pointed out that in his State the drug testing laboratory was not under the State Drugs Controller. He desired to have the views of the committee as to whether the drug testing laboratory should be a part of the Drug Control Organisation.

After some discussion the Committee agreed that in States where there was only a Drugs Testing Laboratory, it should be under the over all charge of the respective State Drugs Controller. This would facilitate sampling programme by the State Inspectorate staff. As the person in charge of the Drugs Testing Laboratory had also to be associated with the screening committee while licensing new formulations in the state it was necessary that he should be a part of the Drug Control Organisation.

(4) Weeding out of irrational and harmful formulations.

It was pointed out that criticism against marketing of a large number of unnecessary and irrational combinations in the country is continued to be made in many a forum. In order to take this problem, the committee decided that the Zonal Officers of the Central Drugs Standard Control Organisation should prepare a list of types of formulations moving in their respective zones and considered to be irrational. In preparing the list, besides the personal knowledge of the Zonal Officers through marketing survey or otherwise, the Indian Pharmaceutical guide could also be made use of. It was also agreed that the list should incorporate the irrational formulations which the ESIS and Army sometimes ordered against tenders. This list should be tentatively prepared within a period of 3 months. Thereafter it should be screened by a Sub-Committee consisting o the following members :-

1. Dr. V. C. Sane, Commissioner, Food & Drug Admn., Maharashtra State, Bombay.	Chairman
2. Dr. J. Das Director of Drugs Control, West Bengal.	Member
3. Shri S. S. Kattisshettar Drugs Controller, Karnataka.	Member
4. Shri C. V. Narasimhan Jt. Drugs Controller, Tamil Nadu	Member
5. Dr. O. P. Sharma Drugs Controller, Delhi Admn.	Member
6. Dr. M. A. Patel Director, Drugs Control Admn. Gujarat.	Member
7. Dr. P. Das Gupta	Convener

Dy. Drugs Controller (I)
North Zone, Ghaziabad.

It was also agreed that the sub-committee could co-opt any expert for the purpose of screening of the list of formulations and also take the advice of the screening committee in their States, if necessary. The finalized list should be placed before the next meeting of the Drugs Consultative Committee and the decision taken in regard to the agreed list of irrational formulations should be uniformly implemented by all State Drugs Control authorities.

(8) Reports on samples of drugs and raw materials tested by approved laboratories.

The Committee agreed that where the approved laboratories carried out only a few tests and declared the samples to be of standard quality in so far as those tests were concerned they should be asked not to give a conclusive report and indicate clearly in the test report the particulars of tests which were not performed by them.

(21) Amendment of Rules 71, 71-A and 76 of the Drugs and Cosmetics Rules laying down that a manufacturer / repacker of drugs shall have his own testing laboratories.

Members wanted to know the decision of the Union Health & Family Welfare Ministry relating to the enforcement of the Rules which require that every manufacture, whether big or small, should establish his own testing laboratory vis-à-vis the representation of the small scale manufacturers.

The Chairman explained that the Ministry of Health & Family Welfare had considered the recommendations made by the Drugs Consultative Committee at its last meeting in consultation with the Union Ministry of Law. Keeping in view the difficulties voiced by units in the small scale sector, Ministry had decided to give a further extension of time to exiting units for setting up their own testing laboratory up to 1st January, 1981. The Ministry of Health have, however, endorsed the other recommendation of the Drugs Consultative Committee that new units applying for licence should be required to comply with the amended Rules and have their own testing laboratories before a licence is granted. He informed the members that a separate communication in this regard was being issued to enable the Drugs Control authorities to take action accordingly.

Shri J.P.I. Singh, Drugs Controller, Madhya Pradesh wanted to know what would constitute sophisticated tests which might be allowed to be carried out at an approved laboratory if the testing unit did not possess the said equipment.

The Chairman agreed to circulate a list of sophisticated equipment involved in sophisticated testing after consultation with the Director, Central Drugs Laboratory, Calcutta and the Director, Central Indian Pharmacopoeia Laboratory, Ghaziabad in the matter.

(43) Revision of Schedule P of the Drugs and Consultative Rules laying down life period of drugs.

The Committee decided that a small sub-committee consisting of the following members should examine the comments received from the State Drugs Control authorities on the subject and give its recommendations before the next meeting of the Drugs Consultative Committee :-

1. Commissioner, F.D.A. Maharashtra State	Chairman
2. Director, D.C.A. Gujarat State	Member
3. Assistant Drugs Controller (India) Port, Bomaby.	Member (convener)

(46) Check on the reuse of glass bottles for filling transfusion solutions.

The Committee reiterated its earlier stand that manufacturers of transfusion fluids may be allowed to reuse U.S.P. Type I bottles provided they have an arrangement of collecting these bottles from the hospitals. But the reuse of U.S.P. Type II bottles should be strictly prohibited.

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

(a) Consideration of the report of the sub-committee to go into the question of the use of plastic containers for packing of liquid oral preparations and to recommend the conditions under which plastic containers should be allowed to be used.

The Committee considered the report of the sub-committee and recommended as under :-

(1) The plastic containers used for packing of liquid oral preparations should be of polyethylene only. No other classes of plastics may be permitted to be used for packing of liquid oral preparations.

(2) The polyethylene containers used should comply with the ISI specifications. The drug manufacturers who use the plastic containers should take a certificate from the manufacturers of the plastic containers that these containers have been tested and conform to ISI standards.

(3) the State Drugs Control authorities should grant permission to the pharmaceutical units for packing liquid oral preparations in polyethylene containers only on submission of data in regard to the compatibility of the containers vis-à-vis the content.

Item 3(b) : Consideration of the report of the sub-committee to draw up standard building plans for manufacture of different categories of drugs, blue prints and guidelines for drug manufacturing units and use of State Drug Control authorities.

The committee considered the report of the sub-committee which included inter-alia Blue Prints in respect of various manufacturing sections together with the Area for each section; the list of machinery required for each manufacturing section and the analytical laboratory; a brief note giving certain special requirements / good manufacturing practices etc. in respect of each section and certain other recommendations for amendments to the Drugs and Cosmetics Rules to enable licensing authorities to deal more effectively with the prospective entrepreneurs applying for licence to manufacture formulations.

The Committee accepted the report of the sub-committee. So far as the areas of the various manufacturing sections as recommended in the report of the sub-committee were concerned it was felt that while the areas recommended by the sub-committee were ideal this should be left to the discretion of the licensing authority vis-à-vis the availability of space in metropolitan cities, the number of products proposed to be manufactured, and the volume of production.

Item 3(c) : Consideration of the items to be permitted for repacking under the Drugs and Cosmetics Rules in the light of comments received from State Drug Control authorities.

The Chairman observed that suggestions regarding additions to and deletions from the list of 65 items that was recommended earlier for repacking were invited so that the list may be revised. But the suggestions received are for additions of a large number of items which are not altogether reasonable. He said that the idea was to allow repacking of items required by doctors, small dis- .....
was readily caused by non-inclusion of the item in the list of drugs for repacking. The intention should be to help such consumers rather than accommodation of small manufacturers. The Committee thereafter agreed to appoint a sub-committee with the following composition to look into the items furnished by the State Drug Control authorities and to draw the revised list :-

1. Drugs Controller, Karnataka Chairman

2.	Drugs Controller, Delhi	Member
3.	Drugs Controller, Gujarat	Member
4.	Commissioner, FDA, Maharashtra	Member
5.	Dy. Drugs Controller (I), South Zone, Madras.	Member (Convener)

It was agreed that the list of drugs once drawn by the sub-committee and approved by the Drugs Consultative Committee should be uniformly implemented by all State Drugs Control authorities. Till then it was also agreed that the status quo should be maintained.

Item 3(d) : Test for pyrogens – consideration of the practices being followed in U.K. and U.S.A.

Replies received from the Chief Pharmacist, Deptt. of Health & Social Security, U.K. and the Commissioner, Food & Drug Admn. U.S.A. were considered by the Committee. It was agreed that parenteral preparations of a volume of less than 10 ml should continue to be excluded from the requirement of the 'Test for Pyrogens.'

Item 3(e) : Consideration of the report of the sub-committee constituted to go into the question of marketing of hard gelatine caps. Containing anti-biotics and other life saving drugs in polyethylene bags.

The report of the sub-committee was considered. The Committee agreed with the recommendation made by the sub-committee that anti-biotics and other potent life saving drugs may be permitted to be sold in retail packing of polyethylene bags containing not more than 25 units of the item. It was also decided that since hospitals consume large quantities of drugs in comparatively short periods, there should not be any restriction as regards the size of the packing but such supplies should not exclusively in plastic bags.

Item 3(f) : Consideration of the report of the sub-committee appointed to study the problems created by the loan licensing system and suggest changes in the Drugs & Cosmetics Rules to remedy them.

Dr. Sane, Commissioner, FDA Maharashtra and Chairman of the sub-committee briefly summarized the salient recommendations, made by the sub-committee. The report of the sub-committee was then discussed at length. The concensus view of the Committee was that loan licensing system should continue with certain restrictions. The committee unanimously agreed to the following restrictions being imposed on loan licensing system :-

1. Drugs and Cosmetics Rules should be suitably modified so as to require that after 2 renewals the loan licensee must set up facilities for the manufacture of all categories of drugs covered by the loan licence.

2. Not more than 6 units should be given loan licensed with a single manufacture.

3. Not more than 10 items per unit should be allowed to be manufactured against a loan licence.

4. No loan licence should be granted to any unit on more than one parent firm.

5. The sub-committee has recommended that no loan licence should be granted for the manufacture of immunological products, surgical dressing, blood and its products, transfusion solutions, medicinal gases, disinfectants, cardiac glycosides, ecbolic preparations, antibiotic parenteral preparations, narcotic and psychotropic preparations and also for repacking of drugs. The Committee recommended that ophthalmic preparations and Injections should also be included in the list of items not permitted to be manufactured against a loan licence.

6. Loan Licensing System should not be exploited by manufacturers having facilities for manufacture to increase their production capacity. Loan licensing is essentially meant for parties who do not have their own manufacturing facilities and have therefore to avail of the manufacturing facilities of other firms.

Item No. 4 : Uniform policy to be adopted for disposing of applications received by the State Drugs Control Authorities for manufacture of New Drugs already approved by the Drugs Controller, India.

The Committee agreed with the Chairman that in respect 'new drugs' which were of recent origin permission should be granted by the Drugs Controller (India) alone and parties approaching State Drugs Control administrations in this regard should be directed to apply to the latter. This was all the more necessary in view of 'New Drugs' now being required to be marketed under generic names only. On the request made by the Drugs Control authorities in Maharashtra and Tamil Nadu it was also agreed that when permission was granted for the first time for the import / manufacture of a 'New Drugs' a copy of the permission letter should be circulated to all State Drugs Control authorities for their information.

Item No. 5 : Quality control over Vaccines.

The Chairman observed that the Vaccine Production Board of the Ministry of Health had recommended that the Drugs Controller (India) might ensure quality control over vaccines manufactured in the country particularly in the private sector. He suggested that a six monthly statement giving information about the number of premises of vaccines manufacturers inspected, the number of samples taken for test, the results of tests, the deficiencies observed during inspection and the action taken, if any, should be furnished by the States to the Drugs Controller (India) to ensure uniform enforcement. This was agreed to by the Committee.

The Director, Drugs Control Administration, Gujarat pointed out that Director, C.R.I. Kasauli took 4 to 6 months time to report on samples of vaccines and urged the Chairman to do something to obviate the delays. The Chairman promised that if Shri Patel furnished facts and figures in writing, he would take up the matter with the Director, Central Research Institute, Kasauli.

Item No. 6 : Quality of oral enzyme preparations.

The Chairman recommended that in the case of preparations containing non-pharmacopoeial enzymes the manufacturers should be required to show on the label of such preparations the enzymatic activity of such enzymes in terms of recognized units. It was also agreed that in order to exercise a close check over the quality of these preparations, frequent sampling should be resorted to.

Item No. 7 : Labelling of combined batch number and date of expiry by manufacturers.

The Committee agreed that in the case of ointment tubes there was no objection to the giving of the date of manufacture and batch number as "combined batch number and date of expiry" by certain manufacturers so long as the relevant provisions under Rule 96 of the Drugs Rules are compiled with by them.

Item No. 8 : Certification of cosmetics under I.S.I. certification marks scheme.

The committee agreed that the I.S.I. standards for the following items of cosmetics may be adopted under the Drugs and Cosmetics Rules :-

1.	IS: 3959 -	1966	Skin powders
2.	IS: 5339 -	1969	Skin powders for infants
3.	IS: 5383 -	1978	Tooth Powder
4.	IS: 6356 -	1978	Tooth Powder

5.	IS: 6608 -	1978	Skin Creams
6.	IS: 7123 -	1973	Hair Oils
7.	IS: 7669 -	1978	Shampoo, Soap based
8.	IS: 7679 -	1978	Hair Creams
9.	IS: 7884 -	1978	Shampoo Synthetic detergent based
10.	IS: 8481 -	1977	Oxidation hair dyes (liquid)
11.	IS: 8482 -	1977	Colonge

Item No. 9 : Consideration of the suggestion that a manual should be prepared for guidance of Drugs Inspectors and Senior Supervisory Officers.

The Committee decided to appoint a sub-committee with the following composition to prepare a manual which could be used by Drugs Inspectors and Senior Supervisory Officers in enforcing the provisions of Drugs and Cosmetics Rules more efficiently :-

Director of Drugs Control, West Bengal.	Chairman
Drugs Controller, Karnataka	Member
Commissioner, F.D.A. Maharashtra	Member
Drugs Controller, Madhya Pradesh	Member
Drugs Controller, Andhra Pradesh	Member
Dy. Drugs Controller (I), East Zone, Calcutta.	Member (Convener)

Item No. 10 : Consideration of the question of giving date of expiry on the label of the drugs included in Schedule C(1).

The Committee agreed that drugs in bulk form included in Schedule C(1) need not be required be labeled with the date of expiry of potency and the Drugs & Cosmetics Rules be amended accordingly. To ensure that the bulk drugs used in the manufacture of formulation are of satisfactory quality manufacturers may be advised to test the material six months prior to its use in pharmaceutical preparations.

Item No. 11 : Problems relating to Drugs (Price Control) Order 1979 and supply position of drugs.

On the 8th November, 1979 the Drugs Control authorities had the benefit of discussing the problems relating to the Drugs (Price Control) Order, 1979, and supply position of drugs with the representatives of Ministry of

Chemicals and Fertilizers and the State Chemicals and Pharmaceutical Corporation of India Ltd., New Delhi. Dr. A. Masood, Deputy Development Commissioner (Drugs) and Shri U. N. Malik, Under Secretary from the Department of Chemicals & Fertilizers and Shri I.D. Chaudhry, Marketing Manager from C.P.C. India Ltd., New Delhi were present by special invitation.

The members raised the following points for clarification / necessary action :-

(a) In para 2(h) of the Drugs (Price Control) Order the term 'Government' has been defined to mean only the Central Government. The definition should be enlarged to cover State Government also to enable State Govts. to enforce the provisions of the Order.

(b) Sale of medicines to Hospital by a dealer who possesses both a wholesale as well as a retail licence needs to be clarified. At what price is he required to sell?

(c) Under the Order "Leader Prices" have been notified in respect of certain packs. There are a large number of firms which have published different prices for different packs which are not in line with the 'leader prices.' Some formula should be evolved for regulating the prices of such packs.

(d) Under para 2 (u) of the Drugs (Price Control) Order, 1979 the term "Sales turn over" has been defined, while in Form 6 the term 'Turnover of formulations' has been used. It requires to be clarified as to how the Annual turn over of formulations of a manufacturing firm is to be computed.

(e) Considerable difficulty is being experienced by leading manufacturers of Intravenous Transfusion fluids in obtaining the basic raw material viz. Dextrose anhydrous (Injectable grade) and Dextrose Mono – hydrate (Injectable grade) in Tamil Nadu. Immediate steps are required to be taken to ensure the availability of the raw materials to avert a severe shortage of life saving intravenous fluids in all hospitals of Tamil Nadu.

(f) Methyl dopa is also reported to be in acute short supply and members wanted to know the steps taken by the Ministry of Chemicals & Fertilizers in regard to shortage of this drug.

(g) Pethidine Injection, a narcotic drug, is very important for patients suffering from cardia in-faraction and must be readily available in Hospitals. Its price should not be regulated on the basis of leader price.

As regards the point raised at (a), Dr. Masood agreed that both the Central and State Governments appointed officers for enforcing the order. He agreed that if necessary they would modify the order to specifically include State Governments also.

As regards (b) about sale of medicines to a hospital, be said that medicines have got a maximum ceiling price fixed. Out of this price there is a certain commission fixed for retailer and the wholesaler. If the seller concerned is a retailer, he is entitled to his commission and if he is a wholesaler, he is also entitled to his commission. But if the supplies are for hospital use and the dealer holds both the wholesale and retail licences, the transaction between such a dealer and the hospital should perhaps be treated as wholesale. But he said that he would examine and clarify the position.

In regard to (c), Dr. Masood stated that a formula was devised on pro-rata basis to work out the prices of the firms whose products do not have their prices in line with the leader's prices and where packings differed. Owing to representations from Industry, the formula was kept in abeyance and the Industry asked to give an alternative formula. The Ministry is seized of the problem and will circulate the formula to all concerned as soon as it is finalized.

In regard to (d), Dr. Masood said that in Form 6, the term 'Turnover of formulations' has been used and it is for the purposes of determining profitability of a firm. The term 'Sales Turnover' used in para 2 (u) of the Order is in regard to exemption of firms from the order. Necessary clarification will be issued as to how the annual turnover of a manufacturer is to be arrived at.

(e) Dr. Masood stated that the Ministry of Chemicals & Fertilizers has been seized of the shortage of transfusions solutions for want of raw materials which are manufactured by M/s. Maize Products Ltd., Ahmedabad and M/s. Anil Starch Products, Ahnedabad while M/s. Maize Products where experiencing labour trouble, M/s. Anil Starch were facing power cuts which had adversely effected their production of raw material. He set up the steps taken by Ministry at the highest level and hoped that supplies of raw materials would be restored by the two firms. He also welcomed any suggestions from the State Drugs Control authorities in this regard and assured the members that these suggestions would be considered favourably.

(f) Dr. Masood stated that there were reports of shortage of Methyl dopa tablets, an anti-hypertensive drug from the State Drugs Control authorities. He observed that the demand catered to is based on last years'

consumption of a drug in the country. This time the demand has exceeded. Shortages of a specific proprietary product were due to the firms insistence on getting the bulk drug from a publication source to which Govt. have not agreed. The Ministry of Chemicals & Fertilizers have made adhoc allocations in favour of certain parties. M/s. Dey's Medical Stores, Calcutta have already formulated certain bulk quantities. M/s. Indian Drugs & Pharmaceutical Limited have been requested to formulate additional quantities. M/s. Indian Drugs & Pharmaceutical Limited have already released sufficient stocks of their Emdopa tablets during the last two months. A watch was being maintained on the production of Methyl dopa tablets.

The representative of C.P.C. said that there is no shortage of Methyl dopa at present. The Chairman asked Shri Chowdhury to inform State Drugs Controllers about the names of the parties to whom the material has been supplied.

(g) Regarding supplies of Pethidine Injection, Dr. Masood agreed with the Chairman that in order to facilitate its ready availability, the leader price of Pethidine Injection requires to be reviewed.

Dr. Masood assured the Drugs Control authorities that their difficulties will be looked into and remedied as far as possible and sought their co-operation in enforcing the provisions of the Drugs (Price Control) Order, 1979 and submission of monthly reports about supply position of drugs in the country. He emphasized that reports of shortage of essential drugs from the State Drugs Control authorities did help the Ministry in divising suitable measures and planning the strategy for ensuring future supplies on an all India basis. He welcomed the opportunity he has had of meeting them in person and having fruitful dialogue on various matters concerning his Ministry.

The Chairman thanked the representatives of the Ministry of Chemicals & Fertilizers and C.P.C., for having taken the trouble of attending the meeting and giving the benefit of their advice to members.

Item No. 12 : Consideration of the question of banning the manufacture of certain pastes for termination of pregnancy.

The Committee agreed that preparations meant for Medical Termination of Pregnancy should not be licensed and should be referred to the Drugs Controller (India) for advice before being licensed. The Commissioner, Food & Drugs Administration, Maharashtra has stopped licensing such preparations and other States should follow suit.

The Drugs Controller, Madhya Pradesh asked for the list of items whose manufacture has been recommended to be banned during the last five years. The Chairman said that he would try to make a consolidated list of such items for his information.

Item No. 13 : Sale of physician's samples by drug dealers.

The Committee noted that Sale or Stocking for sale of physician's sample is prohibited under the Drugs and Cosmetics Rules and agreed that manufacturers and dealers should be apprised that they are liable to be prosecuted together with their medical representatives involved in such instances. Licences of the dealers concerned should be suspended in such cases and the Central Excise authorities should also be informed about these incidents.

Item No. 14 : Consideration of the question of continued marketing of certain combinations of halogenated hydroxyquinolines with other drugs.

The Committee agreed with the decision that Enzyme preprations, digestive or centiflatulence preparations should not be permitted to be manufactured with any halogenated hydroxyl quinoline as an ingredient. The Committee agreed that this decision should be enforced uniformly in all the States.

Item No. 15 : Difficulties / Clarifications relating to Ayurvedic (including Siddha) and Unani medicines and Homoeopathic medicines.

At the request of the Chairman Hakim Razzack, Deputy Adviser (Unani), attended the meeting for giving the necessary clarification regarding indigenous medicines.

(a) Loan Licence for Ayurvedic drugs.

The Committee was of the view that an Ayurvedic loan licence can be given only on an Ayurvedic manufacturer having a licence in Form 25 D.

(b) Question of levy of additional fee for permission to manuacture additional Ayurvedic drugs.

The Committee agreed that the proposal should be referred to the Ayurvedic & Unani Drugs Technical Advisory Board for its consideration.

(c) Question of revising Schedule T on the lines of Schedule M to prescribe requirements of plants and equipment for manufacture of various categories Ayurvedic medicines.

The Committee agreed to refer the proposal to the Ayurvedic Drugs Technical Advisory Board for its consideration.

(d) Status of Ayurvedic, Siddha and Unani drugs manufactured in States where Chapter IV A is not enforced.

The Committee observed that almost all the States have since started enforcing the provisions of Chapter IV A relating to Ayurvedic (including Siddha) and Unani drugs and as such no problem is envisaged on this account.

(e) Consultation with the experts in Ayurveda, Siddha or Unani before the grant of licence in Form 25-D.

The Committee was of the view that the State Licensing Authority may seek the expert's advice on any aspect on which he is not competent, and if he is satisfied he can even reject the application of the firm on the advice tendered by the expert.

(f) Rule 158 relating to conditions of licence to manufacture for sale Ayurvedic (including Siddha) or Unani drug :- Provision for maintenance of inspection book as in Form –35 is to be made.

The Committee agreed that the matter should be referred to the Ayurvedic & Unani Drugs Technical Advisory Board for its consideration.

(g)Question whether 'Attars' should be allowed to manufacture and market Ayurvedic preparations like 'Aruque', 'Murraba', 'Khambera', 'Syrup' etc.

The Committee was of the view that the subject activity is very limited and that status quo may be maintained in this regard.

(h) Amendment of Ayurvedic formulary of India Part I.

It was suggested that in order to bring uniformity in the composition of Ayurvedic drugs, the drugs specified in Ayurvedic formulary of India Part I may be permitted to be manufactured only in the composition given in this official compendia and an amendment to this effect may be made in the Rules.

The Deputy Adviser (Unani) stated that a sub-committee of Ayurvedic, Drugs Technical Advisory Board was reviewing the books of authority included in the First Schedule and considering the question of including the Ayurvedic formulary in the first schedule. The provision of a Rule prescribing the manner of labeling of formulary and shastric preparations

covered by the books of 1st Schedule and also proprietary products was also under consideration of this sub-committee.

(i) Separate Schedule providing space and equipments for Ayurvedic drugs may be laid down.

This item was already discussed vide item 15(c).

(j) Air-conditioning of the Capsule Unit.

The Deputy Adviser (Unani) clarified that air-conditioning of Capulation Unit is necessary for preventing deterioration of hard gelatine capsules. The matter will however be referred to the Ayurvdic & Unani Drugs Technical Advisory Board.

(k) Amendment to Drugs Rule 154 (1).

The Drugs Controller (ISM), Uttar Pradesh expressed his difficulties in enforcing Rule 154(1) because of the different interpretations to which it was subjected by the Ayurvedic drug manufacturers who failed to receive Ayurvedic drug manufacturing licence within a period of 3 months from the licensing authority on account to non-fulfilment of the conditions of Rule 157. He desired that the existing Rule may be changed to read as under :-

"A licence to the manufacturer for sale of Ayurvedic (including Siddha) or Unani drugs shall be issued in 25-D. Subject to the conditions of Rule 157 being fulfilled, the licence shall be issued within a period of 3 months from the date of receipt of the application."

The Deputy Adviser (Unani) stated that in his view, the Rule was quite clear. However, the opinion of the Law Ministry will be obtained in the matter and the member would be informed of the position.

(l) Consideration of the question of deleting Ayurvedic book Rasatantra Sare from the First Schedule of the Drugs and cosmetics Act, 1940.

The Committee agreed to the suggestion and decided that it should be referred to the Ayurvedic and Unani Drugs Technical Advisory Board for necessary action.

(m) Selling of Ayurvedic preparations whose proprietary names resemble Allopathic drugs.

The Chairman pointed out that at the C.C.H. meeting held in January, 78 the Health Ministers had passed a resolution that at the time of licensing of manufacture of proprietary Ayurvedic preparations, the State Licensing Authorities should ensure that they are not marketed under names resembling those of Allopathic products.

The Commissioner, Food & Drugs Administration, Maharashtra did not allow such products to be manufactured in the Maharashtra State. The consensus of the members was to disallow proprietary Ayurvedic products with names resembling those of allopathic drugs to prevent substitution of medicines to the deteriment of the consumer. The licensing authorities should also ensure that the words "Ayurvedic Medicines" should be prominently displayed on the labels of such preparations.

The following additional items were also considered :-

(i) Misbranded Ayurvedic and Unani drugs.

The Drugs Controller, ISM, Uttar Pradesh pointed out that there is no provision in the Drugs & Cosmetics Act regarding misbranded Ayurvedic and Unani drugs, and the Act does not give any legal support to reject misbranded products.

The Chairman clarified that Drugs and Cosmetics Act was being amended to include a definition of misbranded Ayurvedic & Unani drugs and penalties for manufacture and sale of such drugs were being laid down.

(ii) Repacking of Ayurvedic products.

The Committee was of the view that units applying for repacking licence for Ayurvedic drugs shall be asked to take out regular licences for Ayurvedic medicines.

(iii) Ayurvedic eye-drops and surma.

The Deputy Adviser (Unani) clarified that these preparations when manufactured under controlled conditions and according to prescribed standards did not give rise to any side effects and are useful. He promised to furnished the methods of manufacture of these two products to Commissioner, Food & Drugs Administration, Maharashtra so that he could enforce them in the State of Maharashtra. It was agreed that Ayurvedic, Drugs Technical Advisory Board should circulate suitable guidelines to States.

Problems relating to Homoeopathic medicines.

At the invitation of the Chairman Dr. Jugal Kishore, Adviser in Homoeopathy, Ministry of Health attended the meeting for giving the necessary clarification on matters relating to homoeopathic medicines.

(n) Consideration of framing a separate Schedule under Rule 85-E of the Drugs & Cosmetics Rules, 1945.

The Chairman stated that a sub-committee was earlier constituted by the Drugs Consultative Committee to lay down details of the minimum equipment, space, laboratory equipment and the staff to be employed for the manufacture of Homoeopathic medicines and mother tinctures under the Drugs and Cosmetics Rules. The sub-committee had visited the premises of various manufacturers of Homoeopathic medicines in the country and done some useful work. Several of the members were not now with the various administrations and some of them had passed away. Unfortunately the work of the sub-committee was not completed. He suggested that a new sub-committee be constituted to complete the unfinished task of the earlier sub-committee and submit a report after reviewing the earlier data. The Committee agreed to the suggestion of the Chairman and decided to appoint the following sub-committee :-

1. Adviser Homoeopathy in the Ministry of Health	Chairman
2. Director of Drugs Control West Bengal	Member
3. Commissioner, Food & Drugs Administration, Maharashtra	Member
4. Drugs Controller, Delhi Admn.	Member
5. Drugs Controller, Kerala State	Member
6. Dy. Drugs Controller (India), North Zone, Ghaziabad	Convenor

(o) Form 25-C may also be required to contain list of items to be manufactured.

The Committee agreed that Form 25-C should be amended to provide for the inclusion of the list of Homoeopathic medicines in the licence.

(p) Rule 85 relating to conditions of licence to manufacture for sale Homoeopathic medicines.

The Committee agreed that a provision should be introduced in the Drugs and Cosmetics Rules so that all records of Homoeopathic medicines are required to be retained for a period of three years from the date of manufacture.

(q) Uniformity with respect to Homoeopathic Injections.

The Committee agreed that no liquid preparation should be allowed to be marketed in an ampoule or vial and this decision should be implemented uniformly by all the State Drugs Control authorities.

In reply to an enquiry made by the Director, Drugs Control, West Bengal, the Adviser in Homoeopathy said that Homoeopathic preparations in Capsule form should not be allowed to be marketed.

The Commissioner, Food & Drugs Administration, Maharashtra State desired to have the list of Homoeopathic Combination so far approved by the Adviser, Homoeopathy. The Adviser Homoeopathy said that a list of combinations which have been approved and proved to be very useful in actual practice would be made available for the guidance of the State Drugs Control authorities.

The Chairman thanked the Adviser in Homoeopathy and Dy. Adviser (Unani) who had attended the meeting by special invitiation.

Item No. 16 : Consideration of the suggestion that with the intention to enforce Section 42 of the Pharmacy Act and Rule 65 (15) of the Drugs & Cosmetics Rules it should be made obligatory on the part of Chemists to have photograph of approved qualified persons affixed on the licences.

The Committee noted that the Pharmacy Council of India was already seized of the problem and that no separate action was necessary on the part of the Committee.

Item No.17 : Consideration of the question of granting permission to manufacture for export purpose only, a preparation under different names even though the formula of the preparation is one and the same.

The Committee agreed to the proposal that for export purpose only a preparation having the same formula may be allowed to be exported under a different name.

Item No. 18 : Consideration of the question of a policy to be adopted for the grant of loan licences to manufacturing premises for one and the same

product under the same name to cope up with the increased production and demand.

This subject was discussed under Agenda item 3(f) and the decision thereunder would apply to the subject item.

Item No. 19 : Consideration of the question of stipulating a suitable policy to be adopted regarding renewal of licences for which applications are received after a period of six months' of expiry.

This question was considered by the Committee at its 20th meeting and a decision was taken that if the licensees carried on business after a period of six months from the expiry of the licences, legal action may be taken against the defaulting firms. This question was re-examined in the meeting, in the light of the circumstances brought before the Committee by the Commissioner, Food & Drugs Administration, Maharashtra State. The Committee felt that the grace period of six months was sufficient time in which licences could be got renewed by the defaulting firms. In case of defaulting firms the licensing authority may, where there are mitigating circumstances, take a sympathetic view. In such cases rather than legal action, administrative action should be taken by the licensing authorities.

Item No. 20 : Consideration of the question of adopting a uniform policy for the perfumery industry for their compliance of the provisions of Drugs and Cosmetics Act & Rules.

The Committee recommended that the following guidelines as adopted by the Commissioner, Maharashtra State in licensing perfurmery activity may also be followed by other State licensing authorities :-

(i) Minimum space requirements for manufacture should be 100 sq.ft.

(ii) Experienced person should be incharge of manufacture of perfumery compounds.

(iii) The product shall be labeled with the following particulars :-

(a) Name of the product.
(b) Name of the manufacturer and his address.
(c) Net weight/volume/Batch No.
If the contents are more than 60 ml. in the case of liquids, above 30 gm in the case of solids and semi-solids.
(d) Manufacturing Licence No.

Item No. 21 : Consideration of the question of the grant of loan licences for Sterile poweders, whole human blood and blood products.

The Committee unanimously agreed that sterile product whole human blood and blood products should not be licensed against loan licences.

Item No. 22 : Colours to be used in the manufacture of hair dyes / colouring of Csometics.

A question was raised whether the use of bad acetate in metallic hair dyes was in consonance with the provision of Rule 145 (since lead salts are not added for colouring hair dyes but for its after effect to get the desired result) viz-a-viz the current reports of lead poisoning due to its presence in Surma.

The Committee decided that the matter may be examined by the Food and Drugs Administration Gujarat where the manufacturers of such hair dyes are located and furnish a report on the subject. Till them the status quo should be maintained.

Item No. 23 : Consideration of the question of permitting additional products containing (1) higher concentration of active ingredients (2) repacking of toxic chemicals / drugs and (3) additional products containing sub-therapeutic dose of active ingredients for supply against rate contract / tenders from State Government Organisations / Railways / Defence Ministry etc.

The Committee was of the view that formulations with irrational formulae should not be allowed to be manufactured by the licensing authorities in their respective States even against tenders from State Governments / Central Govt. bodies. The licensing authorities should alone decide in what strengths the products should be allowed to be manufactured. Issuing a general circular to the various bodies concerned will not serve the purpose. Instead, instances should be brought to the notice of the Drugs Controller (India) so that latter can take up the specific issues with the department concerned.

Item No. 24 : Consideration of the question of licensing of godowns of banks where drugs and pharmaceuticals are pledged by manufacturers and dealers of drugs.

It was agreed that a copy of the Supreme Court Judgement cited by the Commissioner, Food & Drugs Administration, Maharashtra on the subject may be supplied to the Drugs Controller (India) so that the matter may be examined in consultation with the Law Ministry.

Item No. 25 : Consideration of the question of charging of extra fees for granting Drug Licences in the event of change in the constitution of the firm.

The Committee felt that the condition attaching to licences in various forms e.g. 20, 20-A, 20-B, 21, 21-A and 21-B that the licensee should take a fresh licence in the event of change of constitution of the firm within a period of 3 months from the date from which the change takes place should be modified so as to provide that the licensee should apply for a fresh licence within the stipulated period. This period may also be extended from 3 months to 6 months and a provision made for levy of penalty on the licensee in case he does not apply for the licence within the period prescribed. The Chairman stated that he would examine the matter.

Item No. 26 : Manufacture and use of Gudakhu.

The Committee felt that it might be difficult to ban the use of tobacco in dental preparations and decided that as a first step manufacturers should be informed that the use of tooth paste / powder containing tobacco is fraught with the risk of cancer and should be dissuaded from marketing such products. As a second step a cautionary note such as "This preparation contains tobacco. Use of this preparation is injurious to Health" should be required to be displayed on the label of this preparation to protect the health of the public. Thirdly in States of Madhya Pradesh and Orissa where the use of this preparation is widely prevalent, the manufacturers may be asked to limit the content of tobacco in Gudakhu such that the Nicotine content of the product is between 1% and 1.25% or the tobacco content is from 12% to 22%.

Item No. 27 : Amendment of sub rule 11-A of Rule 65.

The Committee agreed to the existing sub-rule 11-A of Rule 65 being amended to read as 'No person, dispensing a prescription shall supply any other preparation whether containing the same substance or not in lieu of the drug prescribed', to prevent the supply by a Chemist of a drug other than that prescribed by an R.M.P.

Item No. 28 : Amendments to Schedule C and Schedule C(1).

The Committee agreed that entry 11 in Schedule C and entry 9 of Schedule C(1) be modified to replace it by a general entry "Antibiotics" which would cover all antibiotics. The specific names of antibiotics as mentioned in these Schedules would be deleted.

Item No. 29 : Acton taken on Test Reports declaring a samples of a drug to be not of standard quality.

The Committee decided that where cases of drugs reported to be not of standard quality by a Govt. Analyst are of a serious nature the matter may be taken up by the Drugs Controller of the State where the sample was

drawn demi-officially with the Drugs Controller of the State where the manufacturer is located and should be pursued vigorously. In less serious cases the existing procedure of bringing cases to the notice of the respective licensing authorities for appropriate action may continue to be followed.

Item No. 30 : Amendment of Form 21-A to exclude drugs specified in Schedule C.

The Committee agreed to delete reference to Schedule C from Form 21-A and recommended that the Form 21-A may be amended accordingly.

Item No. 31 : Enforcement of uniform strengths for the various dosage forms.

The Committee recommended that in respect of pharmacopoeial preparations the manufacturers should be asked to market the preparation in the useful strength given in the pharmacopoeia.

Item No. 32 : Standards for soft extracts.

Shri Narasimhan, Joint Drugs Controller, Tamil Nadu informed the Committee that certain manufacturers were using soft extracts in the manufacture of galenical preparations in his State while no standards were available in any recognized pharmacopoeias for these soft extracts. He was of the view that the manufacture of tinctures from soft extracts may be allowed in cases where pharmacopoeia prescribes a definite test or assay procedure to evaluate the active ingredient and in all other cases the manufacture of tinctures etc. from soft extracts should not be allowed.

The Chairman stated that the matter requires to be examined in depth and certain information had already been called from the Drugs Controller, Tamil Nadu to facilitate consideration of the question.

Item No. 33 : Minimum requirements for testing laboratory.

The Committee appointed a sub-committee with the following composition to lay down the norms regarding minimum requirements of space and equipments in respect of institutions which carry out tests on drugs, cosmetics or raw materials used in their manufacture on behalf of licences :-

1. Director, Central Drugs Laboratory, Calcutta.	Chairman & Convener
2. Director, Central Indian Pharmacopoeia Laboratory, Ghaziabad.	Member
3. Officers in charge of the Govt. Testing	Members

Laboratories of Maharashtra, Gujarat
and Karnataka

Item No.34-35: (i) Misuse of wholesale licences.
(ii) Loan licences for splrituous preparations.

As the Drugs Controller, Haryana was not present, the items proposed by him were not taken up for consideration.

Item No. 36 : Standards of Cosmetics – Consideration of the question whether microbial count in the case of Cosmetics should be insisted upon.

The Committee agreed that till Drugs and Cosmetics Act lays down standards for cosmetics, the standards on microbial count need not be enforced.

Item No. 37 : Implementation of Schedule 'V'.

The Committee recommended that all patent and proprietary medicines containing vitamins would be covered by Schedule V and no exemption in the case of any agency or State Government body could be made.

Item No. 38 : Review of prevailing formulation of Analgin Injection.

It was decided that the question of permitting the continued marketing of Analgin Injection in the present prevailing strength vis-à-vis eh strength of Analgin Injection as prescribed in the U.S.S.R.P. should be examined in consultation with experts.

Item No. 39 : Delay in furnishing reports of Injection by Zonal Officers.

The Chairman pointed out that the Zonal Officer and not the Drugs Inspector was responsible for the inspection reports and as such the inspection report could only issue after his perusal. He agreed however that after the Joint Inspection was over, the repport should be prepared jointly as far as possible.

Item No. 40 : Ambiquities in recently amended Drugs & Cosmetics Rules.

The Chairman clarified that private cars with specific registration number which was regularly used to transport drugs could be licensed but a taxi or a private car used once in a while to transport drugs need not be licensed.

Item No. 41 : Disposal of Cosmetics found to be of standard quality.

The Chairman clarified that samples of drugs as well as cosmetics found to be of standard quality and lying with the Drugs Control Department cold be given to Government Hospitals for use.

Item No. 42 : Consideration of the question of permitting manufactures to manufacture tablets preparations which are official in the pharmacopoeia in the form of capsules.

The Committee recommended that where a drug preparation is official in the pharmacopoeia in the form of a tablet, it should not be licensed to be manufactured in the Capsule form and the decision should be uniformly implemented by all State Drugs Control Authorities.

Item No. 43 : Consideration of granting permission to manufacture primaquine tablets with more than 2.5 mg base.

Dr. R. G. Roy form the National Malaria Institute, New Delhi explained the reasons for insisting that Primaquine tablets should be marketing in 2.5 mg strength only. He stated that the daily dose of the drug was 15 mg. In hospitals and dispensaries the drug is administrated to a patient directly under the supervision of the doctor and for operational difficulties higher strength tablets (7.5 mg
.... mg) were being used. However, in general practice doctors are accustomed to prescribe a drug thrice a day and so on. If higher strength tablets were marketed it could lead to over dosage resulting even in fatalities. The Committee agreed that the present practice of permitting the marketing of only Primaquine tablets containing 2.5 mg base should continue.

Item No. 44 : Consideration of the question regarding addition of colours in I.P. Products.

The Chairman clarified that the Indian Pharmacopoeia Committee had considered this question and had not recommended the use of colours in pharmacopoeial preparations where the pharmacopoeia did not specifically permit the addition of any colour.

The Committee agreed with the Chairman that addition of colours in preparations covered by I.P. should not be permitted unless the individual monograph permitted the addition of colour and the decision should be uniformly implemented by the State Licensing Authorities.

Item No. 45 : Introduction of the word "alongwith the documentary evidence" in Section 18-A of the Drugs & Cosmetics Act.

It was decided that the matter needed examination in detail.

Item No. 46 : Packing of transfusion solutions in plastic containers.

The Committee agreed that implanation test need not be insisted for plastic containers used in the manufacture of transfusion solutions.

Item No. 47 : Consideration of the question whether separate space and equipment is necessary for the manufacture of very small quantity of Ampicillin preparations.

The Committee felt that a separate area and equipment was necessary for the manufacture of Ampicillin preparations irrespective of the fact whether manufacturing operations are big or small.

Item No. 48 : Sale of drugs by wholesaler in split quantities.

The Committee felt that wholesaler should not be allowed to sell drugs in split quantities and licensing authorities should ensure that they sold drugs in an opened containers.

Item No. 49 : Use of demineralised water of liquid orals.

The Chairman while agreeing that demineralised water should be used for the manufacture of liquid oral preparations observed that unless the demineraliser was regularly cleaned and fumigated it would itself become a source of contamination. The Committee recommended that the licensing authorities should ensure that the requirement under Schedule M for water still or deionizer was strictly enforced so that purified water was used in the manufacture of liquid oral preparations.

Item No. 50 : Use of second hand vials for the manufacture of parenteral and ophthalmic preparations.

The Committee strongly recommended that in no case second hand vials should be allowed to be used for vialling parenteral and ophthalmic oral preparations.

Additional Items

Item No. 51 : Labelling requirements of absorbent cotton wool I.P. for smaller packs.

As per I.P. small packings of absorbent cotton wool are required to be sterilized and labeled as 'sterile.' It was brought to the notice of the Committee that such packings available in the market are invariably non-sterile as manufacturers find it difficult to sterilize them.

It was decided that manufacturers should be asked to label the small packings as 'sterile', only if they can guarantee their sterility, otherwise manufacturers should be advised to label their products with the words "To be sterilized before use."

Item No. 52 : Opening of chemists shops during night hours.

The Chairman clarified that the recommendation of the Drugs Consultative Committee to all the chemists who operate during the night to charge on an additional 'service charge' had not found favour with the Ministry of Chemicals and Fertilizers. They are of the view that the opening of shops in the night is a necessary service which chemists must render by opening of their shops by rotation rather than taking recourse to an extra incentive which could be misused. Enquiries made by the Chairman revealed that only a few chemists in various cities of the country are operating during night hours by rotation and the number of shops opened in these cities during night hour is as under :-

Bombay	-	6
Madras-	1	
Calcutta	-	4 to 6
Bangalore	-	4
Hyderabad	-	nil
Delhi	-	8
Ahmedabad	-	4

Item No. 53 : Microbiological Assay Method for Medicinal Crystal violet.

The Director, Food & Drugs Administration, Gujarat asked about the findings of the Chairman in regard to the method furnished by him on the subject. The Director, Central Indian Pharmacopoeia Laboratory, Ghaziabad with whom the method is under examination stated that the method is still under verification and needs to be counter-checked at three or four centres for its uniform results. However, he would try to expedite the studies.

The Chairman stated that if 3 to 4 laboratories accept the method, it will be sent to I.P. Committee for its adoption in the Indian Pharmacopoeia.

Item No. 54 : Delay in payment of bills for testing fees due to C.I.P.L., Ghaziabad.

The Chairman brought to the notice of he members that those States who had appointed officers of Central Indian Pharmacopoeia Laboratory, Ghaziabad as Govt. Analyst had not cleared their outstanding bills for testing fees inspite of repeated reminders from the laboratory. In some

cases the areas pertain to periods 1974-75 and even earlier with the result that the laboratory had been subjected to adverse criticism by the audit authorities. A statement of the outstanding bills for testing charges in respect of various States were read out by the Chairman.

The Chairman urged the members to look personally into the matter and see that the outstanding bills are cleared as possible.

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

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