MINUTES OF THE 25TH MEETING OF THE DRUGS CONSULTATIVE COMMITTEE HELD ON THE 10TH & 11TH SEPTEMBER 1987

Dr. Prem K. Gupta, Chairman welcomed all the members attending the meeting and requested that each members may please introduce himself. He informed that Miss Mira Seth, Addl. Secretary of the Ministry of Health & Family Welfare had inspite of her busy schedule, kindly consented to meet the members of the committee and say a few words on enforcement of Drugs Control in the light of thinking of the Government and also the discussions which are held from time to time in Parliament so that these points are borne in mind when the committee delibtrates and take decisions.

Miss Mira Seth, Addl. Secretary (Health) stated that before she could suggest any measure on drug control, it is necessary to assess how is the present system working and how we could improve upon it. Her approach would be purely an administrative one because she was not a technical person. She has assessed that the number of drugs inspectors in the State was not adequate as per the recommendations of the Task Force. We should have around 2600 drug inspectors in the whole country as against about 600 drugs inspectors. On a further analysis the number of drug inspectors in the State of Uttar Pradesh, Bihar and Madhya Pradesh were less. The number of drug inspectors in these States should be augmented by about 25-30 every year if the optimal minimum has to be maintained. There should be Mobile Squads in each State to detect the cases of manufacture and sale of spurious drugs. This is a very good measure to combat the menace of spurious drugs in the country. She also stated that clinical screening committees to screen formulations of drugs permitted to be manufactured in the state should be set up since many of the States do not have such committees.

She also stated that many of the States like U.P., Bihar, Madhya Pradesh, Delhi either did not have an their own drug testing facilities or the facilities were totally inadequate. Without drug testing facilities, the drug control enforcement is crippled. She suggested that the drug inspectors should take more samples of drugs and also carry out inspection of the manufacturing activities at the end of every year. It would not be proper for any inspector to draw more samples at the end of the year to fulfill any target, but the sampling target should be fixed for every quarter for every drug inspector. This will give more teeth to enforcement. She regretted that many drug manufacturers have not yet set

up their own drug testing facilities, inspite of the fact that the Drugs and Cosmetics Rules now specifically laid down that each drug manufacturing unit shall have its own testing laboratory. This should not be permitted. She observed that prescription drugs namely those included in Schedule 'H' to the Drugs & Cosmetics Rules are freely available from chemists and there is hardly any enforcement of the Rules by the State authorities. She suggested that strict action should be taken to ensure that no prescription drugs are sold freely. Referring to the New Drugs Policy, she observed that the State Drug Control authorities have already been apprises of its salient features and the draft amendments on Good Manufacturing Practices, on new drugs, and loan licensing have already been published for public comments. The report of the committee on Drug Packaging is also being finalized. The Drug Prices Control Order, she observed, should also be enforced by the State Drug Control Authorities. Watch is to be kept to check the increase in prices of drugs which are not included in Schedule I and Schedule II of the D.P.C. Order. The States will have to act as watch dogs to see that the common people is not overcharged, prices of drugs or that no drug should go underground. She appealed to the State Drug Controllers for motivation and dedication of their services and for also canalizing the same by their staff members so that the common man could be helped. The full text of the speech of the Addl. Secretary (Health) is at **Appendix I**.

The Chairman thereafter requested Dr. A. K. Mukherjee, Addl. Director General of Health Services to kindly say a few words to the members attending the meeting. Dr. Mukherjee welcomed the members and informed them that Dr. G. K. Vishwakarma, DGHS was not keeping well and so he could not come to meet the members attending the meeting. He stated that the recent case of supply of adulterated glycerine in J.J.Hospital Bombay had shown how severe the collousness could be if there is laxity in drug control enforcement to control the quality of drugs. He stated that in the Dte. General of Health Services the list of drugs for supplying to the CGHS, to the primary Health Care Centres have been drawn up. It is necessary that the National Formulary of India should be updated so that hospitals could buy drugs with the formulae given in this book. He suggested that the incidence of spurious drugs and sub-standard drugs now prevailing in the country should be reduced and this committee should engage its attention to this problem. More testing laboratories should be set up by the States, if not already done, and Mobile Squads should also be formed to combat the menace of spurious drugs. No manufacturing licence should be granted unless the manufacturer has his own testing laboratory and he follows Good Manufacturing Practices. Referring to irrartional formulations, Dr. Mukherjee stated that each Stae should have a committee to weed out irrational formulations if the States enforce these measures they will strengthen the hands of the Drug Controller (India).

He also endorsed the views of Miss Mira Seth, Addl. Secretary (Health) that strict action should be taken if any chemist is found to sell prescription drug openly. Such sale of potent drugs leads to self-medication by patients without knowing the consequences.

Shri V. S. Subramaniyan, Jt. Secretary (Health) at this stage could come to the meeting and the Chairman requested him to address the committee. Shri Subramaniyan stated that the draft amendment recently published to the Drugs and Cosmetics Rules

gives a new definition of new drugs which includes also combinations if any state drug controllers gives manufacturing licence to manufacture irrational combinations indiscriminately. Such drugs will move to other States and it would be very difficult to curb the manaufacture of similar drugs in other States. He, therefore, suggested that the members who are State Drug & Licensing Authorities should be very careful in granting licences to drug combinations which should be done in terms of the new provisions. He stated that emphasis should be on the quality of drugs. For this purpose every drug manufacturing unit should have its own testing laboratory.

There had been suggestions for group testing laboratory and this matter should be discussed by Drugs Consultative Committee. The Drugs Controller, India had in some cases written to the States to ensure that the 'contraindications' should be shown on the label. He enquired whether thers directions are being followed? He also brought to the notice of the Committee that for new drugs the generic names will have to be shown in double the size of the brand names and for others it has to be shown more prominently and whether these requirements are being complied with by the drug manufacturers it their States. He emphasized about the consumer education and was of the view that unless the consumers are educated about the existing Drug Laws, the drug control in the country could not be effective. He reminded the members that the Health Ministry are anxious to get montly information on drug control enforcement in each State in the proforma given by the Drgu Controller (India) and it appears that many of the State are not giving this information. He stated that the samples drawn by the drug inspectors should not be of the same type of drugs but should be of different categories. Referring to the Asstt. Drugs Controllers of the Central Drug Standard Control Organisation, he stated that they should give information of import of Sera and Vaccines to the Drug Controller (India) regularly. He also mentioned that in some States the Govt. Analysts are not having qualifications as laid down in the Drugs & Cosmetics Act & Rules and as such the test reports of these Govt. Analysts would be not reliable. He requested the members to consider the points mentioned by the Addl. Secretary (Health) and the Addl. Director General of Health Services alongwith those mentioned by him while considering Agenda items and take necessary decisions.

The State Drugs Controllers of M.P., Bihar, Rajasthan, Punjab and Haryana gave an assessment of their drug inspectorate and testing facilities. Request was made for financial help by the Central Govt. for augmenting the State Drug Laboratories. The Drugs Controllers, Bihar, requested that a competent technical person fulfilling the qualification laid down for Govt. Analyst may be suggested so that he could be appointed as the Director of his State Drug Laboratory. Dr. S. K. Roy, Director, Central Drug Laboratory, Calcutta stated that he has one such person who will be willing to join the post on a pay of Rs.4,500/- per month after a few months. The Drugs Controller, Bihar stated that he would take further action after getting in touch with Dr. Roy.

After the inauguration session was over, Dr. Prem K. Gupta, the Chairman stated that the figure of sub-standard drugs prevailing in the country as per the test reports is very high and it is necessary that this figure should be reduced. This could be achieved if the drug inspectors take more stringent action to check the quality of drugs which are

manufactured by ensuring the discipline laid down in the drug control measures right from the beginning of manufacture. In case there is any test report received by any State Drug Controller for any sub-standard drug, stringent action could also be taken against the manufacturer. The entire matter needs re-thinking. The number of drug inspectors today is also 25% of the optimal number in many of the States and efforts should be made to have more inspectors. In many States licences to manufacture irrational drug combinations have been given freely in the past. The committee should be constituted in each State with pharmacologists and clinicians to examine the drug combinations proposed to be manufactured. The World Health Organisation has clearly stated that combination products should be discouraged. The State Drug Controllers shold also take action to de-license irrational drug combinations so that these products no longer flood the market. He stated that when asked in various forums and by Govt. as to why the prescription drugs are sold freely, he has no reply to give. Recently in the public hearings on combination products Oestrogen and Progistrons, he had to hear repeatedly that there is no control over the sale of these products and these prescription drugs are sold freely and openly without prescription by the chemists and no action is being taken against the dealers. If some licences of such dealers are cancelled or suspended this will have some salutary effect. He stated that recently a draft amendment on new drugs, their import and manufacture and also on G.M.P. have been published for public comments and the State Drug Controllers may send their comments at the earliest. In particular he requested the State Drugs Controller to impress upon the small scale manufacturers to conform to the new provisions for their own benefit. He also suggested that the State Drugs Controllers should take the help of the Zonal Officers of the CDSCO for more joint inspections of manufacturing premises. The Chairman stated that Dr. S. S. Gothoskar, who was Drugs Controller (India) for more than a decade was also the Chairman of the Drugs Consultative Committee for 11 years. If the members agree the D.C.C. would record the appreciation of what is done by Dr. S.S.Gothoskar as its Chairman in the past. The members agreed to this suggestion.

At this stage Shri Gopal Krishan Murthy, Drugs Controller, Andhra Pradesh welcomed Dr. Prem K. Gupta as the new Chairman of the D.C.C. and on behalf of the members stated that during his Chairmanship this committee will also do valuable work for proper enforcement of drug control for the benefit of the people. The other members joined Shri Murthy in welcoming Dr. Prem K. Gupta as the new Chairman.

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 of the last meeting were confirmed with no change.

Item No. 2 : Consideration of the statement on action taken on the recommendations made by the Drugs Consultative Committee at its last meeting held on the 8th and 9th Jan. 1985.

The Chairman stated that action taken on the recommendation made at the last meeting of the Drugs Consultative Committee was set out in Annexure I and the members could seek clarification and make observations on any point given in the statements. Regarding Item 5 of the statement about manufacture of preparations containing insoluble Bismuth salts and also combination of Ethambutol with Isoniazide given at Item No. 9, it was explained that these 2 preparatons will be considered by the sub-committee on irrational preparations on the basis of the replies received.

Regarding Item 4 of the statement, the Drugs Controller, Delhi and the Director Drugs Control Administration, Gujarat stated that they have also obtained the opinion of the Law Ministry of their State Government and these would be forwarded by them so that the matter could be examined further.

Regarding Item 10 of the statement it was re-emphasised that the re-use of type II bottles should eb stopped immediately and all State Drug Controllers should take action in the matter.

Item No.3(A):Consideration of the points arising out of the minutes of the last meeting of the Drugs Consultative Committee held on 8th and 9th Jan. 1985.

The report of the sub-committee was accepted.

Item No. 3(B) i) : Report of the sub-committee constituted by the 23rd Meeting of the Drugs Consultative Committee to suggest condensed training courses for B.Sc. as well as B.Pharma Graduates taking into consideration the course outlined by the earlier sub-committee.

Nor many comments have been received on the report which was circulated to the State Drugs Controllers. The report of the sub-committee was approved.

Item No. 3(B) ii) : Report of the sub-committee to permit one testing laboratory for testing the drugs manufactured by a group of manufacturers.

The recommendation sof the sub-committee that these drug manufacturing units may have a group testing laboratory was not accepted.

In view of the present thinking and also because the new provisions of the Drugs and Cosmetics Rules require that each drug manufacturing units should have its own testing unit. But if a drug manufacturer has its sister concern with the saem Managing Director or Director in the same

premises, one testing laboratory can cater to the testing requirements of the same group of sister concerns in the same premises.

The Director, C.R.I. Kasauli stated that in West Bengal two Govt. laboratories are manufacturing Rabbies Vaccines and Cholera Vaccines separately and can one testing laboratory serve both these manufacturing laboratories. The Chairman stated that this specific matter will have to be examined.

Item No. B(iii) : Report of the Sub-Committee to lay down details of space, equipment, etc., for the manufacture of cosmetics.

The report of the Sub-Committee was agreed to.

Item No. 3(B) (iv) : Reprot of the Sub-Committee on licensing under the Drugs and Cosmetics Rules for manufacture of diagnostic reagents.

It was observed that a large number of diagnostic reagents were included in the list by the Sub-Committee. Therefore would need re-examination. The Sub-Committee was re-constituted with the following members :

1.	Dr. S. N. Saxena Director, CRI Kasauli	Chairman
2.	A pathologist to be co-opted by the Chairman	
3.	Dr. L. V. Kannan, Dy. Drugs Controller, India, DGHS Nirman Bhawan, New Delhi.	Convener

It was also suggested that some invitro chemicals used in diagnosis could be excluded from the list. Pregnancy test kits should, however, be considered as drugs. The report of the sub-committee should be submitted within 6 months.

Item No. 3(B) (v) : Reprot of the Sub-Committee to go into the details of manufacture of surgical dressings and to suggest minimum hygienic conditions required for the manufacture of surgical dressings / bandages.

The report was accepted.

Item No. 3 (C) : Weeding out of fixed does combinations of drugs.

The Committee agreed to the recommendations made in the report ot the Sub-Committee.

At this state the Chairman informed Dr. S. N. Saxena, Director, CRI Kasauli had another meeting and he would like to say a few words about testing of Sera and Vaccines. Dr. Saxena stated that whenever a sample of Sera or Vaccine is sent to CRI Kasauli, the Drug Inspector or the State Drug Controller should clearly indicate as to whether all the tests should be done or only some tests should be done that would help in the testing of the drugs and for early issuance of test reports.

At his suggestion Item No. 67 was taken up for consideration.

Item No. 67 : Inspection of manufacturing premises for vaccines and sera.

The Chairman stated that the earlier inspection Panel has now become defuntt. Now whenever Dr. Saxena, Director, C.R.I. Kasauli has to go for inspection of any manufacturing unit he may take his own experts. Dr. Saxena stated that he would prepare a Panel of about 10-12 experts whose services could be utilized by him. It was further explained by the Chairman that for veterinary drugs a separate panel of experts would be formed after consulting the Director I.V.R.I.

Item No. 4 : Manufacture, sale an distribution of formulations containing protein hydrolysates, vitamins, minerals.

All the members were unanimous that the formulations containing protein hydrolysate, vitamins and minerals are "Drugs" and are circumventing the provisions of the Drugs & Cosmetics Act and Rules. Many of these products are given in dose also on the label. It was decided that all such items should be considered as drugs and manufactured under a drug manufacturing licence under the Drugs and Cosmetics Rules. If any party wants any exemptions he should obtain permission from the authorities enforcing the Prevention of Food Adulteration Act and also label the product as 'not for medicinal use' and no dose should be given on the label. Further such food products should not be allowed to be manufactured in the same premises where drugs are manufactured.

Item No. 5 : Manner of labeling Schedule 'P' drugs.

The Chairman informed that Schedule 'P' to the Drugs and Cosmetics Rules laying down the life periods to different thermolabile drugs has already been revised and the amended Schedule 'P' is in force now for about 1 ½ years. Unfortunately many of the State Drug Controllers were not aware of the new provisions, he requested them to study the provisions and revised Schedule 'P' and enforce them. The Commissioner, Food & Drugs Administration, Maharashtra stated that since Rule 96 and Schedule 'P' have been amended it would be in the fitness of things that these provisions should be enforced. If, however, at any place the temperature

is above 25 degree C, it will be necessary for the chemist to install an air-conditioner. The Drugs Controller, Rajasthan however stated that in his State the normal temperature in some months and even in spring and autumn is so high that it would be quite difficult even for reputed chemists in big cities in his State to keep drugs below 25 degree C. He regretted that it will not be possible for him to enforce the provisions of Schedule 'P' in respect of maintenance of drugs below 25 degree C by the chemists. The Commissioner, Food & Drugs Administration, Maharashtra stated that when the Rules have been framed these should eb enforced and no exemptions to any party can be given.

Item No. 6 : I.S.I. specifications for finished cosmetics.

The Committee observed that there will not be any difficulty in complying with the standards for chemists as laid down by the I.S.I. and the minimum standards could be expected under the Drugs & Cosmetics Rules.

A suggestion was made that the I.S.I. has laid down specifications for toilet soaps and these also should be adopted under the Drugs and Cosmetics Rules. This suggestion was accepted.

Item No. 7 : The standards of Weight and Measures Act 1977 and the standards of Weights and Measures (PC) Rules 1977 – applicability to packaging of drugs.

The committee considered at length the provisions of the Weight and Measures Act 1977 which run counter to the provisions of the Drugs & Cosmetics Rules. It was clarified that the packing of any drug, tablet, capsules or liquids is for one treatment and could not be necessarily be in terms of the matric system i.e. a multiple of 5 or 10. It would therefore be necessary for the manufacturers to comply with the provisions of the Drugs & Cosmetics Rules in the matter of packing of drugs. The drugs should therefore be exempted from the provisions of the Weight and Measures Act 1977 and the matter may be taken up with the concerned authorities.

Item No. 8 : Use of approved colour mixtures – manner of labeling.

The question of granting exemptions to the names of colours used in the manufacture of drugs and the label was discussed and it was the view that since the Government analyst would test the presence of each colour in the drug, it would not be proper to give any exemptions. The name of colours should therefore be shown on the label in terms of the provisions of Rule 127 of the Drugs & Cosmetics Rules. If any exemptions is granted the members were apprehensive harmful colours could also be added and

ultimately this will the users. Further the mixing of different colours should not be encouraged.

Item No. 9 : Request for insisting for the sale of Oxytocin Injections for Veterinary use against prescription of a Registered Veterinary Medical Practitioner.

The misuse of Oxytocin by the Milkmen who administer the injection to the cow or buffalow was voiced by many members. The committee reviewed the earlier circulars which were issued to check this menace. After detailed discussions it was agreed to take the following course of action :-

1) Oxytocin of veterinary use should be banned under the Section 26A and necessary action may be initiated.

2) Oxytocin for human use shall be permitted but its sale shall be strictly against prescription of registered medical practitioners. If any dealer is found to sell such oxytocin injection to any milkmen or others, strict action against him shall be taken.

3) The manufacturer of Oxytocin injection for human use could be restricted by the Drugs Controller (India) by advising less import of the raw material i.e. oxytocin in powder form which is imported. The import of this item in bulk should also be only on the recommendations of the Drugs Controller (India).

Item No. 10 : Issue of licence to Bachelor of Science for opening a Medical shop.

Since the dispensing of drugs is a specialized activity for which institutional training is necessary, it would not be considered appropriate to permit a Bachelor of Science to work as a competent person for the sale of drugs. The proposal was not agreed to.

Item No. 11 : Consideration for reservation diagnostics kits, reagents and strips for exclusive development in the small scale sector.

The Committee did not agree to the suggestion that diagnostic kits shall be reserved for the small scale sector only. Diagnostic kits are very sensitive items on which human life depends and the large scale manufacture who can afford research and who can enforce more quality should also continue to manufacture these items.

Item No. 12 : Consideration of the question of showing the name and address of the manufacturer where the drug has been manufactured on the label of the drug.

The Committee discussed in detail the manner of showing the name and address of the manufacturers on the label. It was the consensus view that the name of the manufacturer and the address of the premises where the drug has been manufactured should alone be mentioned on the label.

Item No. 13 : Schedule K of the Drugs & Cosmetics Rules.

Item No. 14 : Procurement of Government Analyst.

Since these items were suggested by the Drugs Controller, Assam who was not attending the meeting, these were not discussed.

Item No. 15 : Combined Food and Drug Laboratory, Agmaquan, Patne – Appointment / deputation of Govt. Analyst.

This matter was already discussed earlier and the Director Central Drugs Laboratory had promised to help Drugs Controller, Bihar in availing of the services of a suitable technical personnel to work as incharge of his drug testing laboratory.

Item No. 16 : Fixation of time limit for analytical chemist for approval.

The Committee was of the view that this was a matter of discretion on the part of the licensing authority and it would not be appropriate to fix any time limit.

Item No. 17 : Necessary instruction may be given to CDL Calcutta and CIPL, Ghaziabad for testing samples of drugs sent from this State (Bihar). At present samples are not accepted in these laboratories.

The Chairman stated that the samples of drugs received from Bihar could not be tested because of the huge arrears of the State Governmetn for the samples tested earlier. However, DC(I) requested the Director, CDL Calcutta and the Director CIPL, Ghaziabad to help the Drugs Controller, Bihar as far as possible.

Item No. 18 : Formula Bank may be constituted at the Central level to eliminate irrational, incompatible harmful formula.

The central Drugs Standard Control Organisation is already considering ways and means so that there is some central guidance for approval of formula of drug combinations.

Item No. 19 : Manufacturing and marketing of Paed. Aspirin tablets.

The committee was of the view that Aspirin tablets for paediatric use should not be permitted. The permission to manufacture 75 mg Aspirin tablets should be withdrawn by persuading the manufacturers. In case there are any representations then this matter could be referred to the medical experts for their advice and the item brought back for discussion in the Drgus Consultative Committee meeting.

Item No. 20 : Vet/Food Supplement.

Since the Drugs Controller, Chandigarh Administration, Chandigarh was not present this item was not discussed.

Item No. 21 : Tablet and capsules sizes for different strengths of the same drug.

The Chairman explained that in the Indian Pharmacopoeia 1955 different sizes of tablets of different strengths have been given in the general monograph. When an amendment in the Indian Pharmacopoeia is considered the provisions in the British Pharmacopoeia will also be taken into consideration. Dr. J. L. Kaul stated that today the same tablet of same strength is marketed in different colours with 5 different brand names and this must be stopped. The Chairman stated that a circular to this effect will be issued by the Drugs Controller (India) for taking necessary action.

Item No. 22 : Powers to be given to Licensing Authorities in States.

It was agreed that necessary amendment may be made in the Drugs & Cosmetics Rules.

Item No. 23 : Amendment of relevant rules like 69, 71, 76, etc.

The Chairman stated that this matter will be examined and further action would be taken.

Item No. 24 : Appeal to the State Government.

Item No. 25 : Amendment of Rule 154.

Item No. 27 : Banning of Ayurvedic preparation containing high percentage of Alcohol which are being abused for intoxicating purposes.

These steps (3 items) related to the enforcement of control measures over Ayurvedic and Unani drugs and as such have to be referred to the Consultative Committee for Ayurvedic, Siddha and Unani Drugs for consideration.

Item No. 26 : Sale of life-saving drugs in Polythene bags.

The committee was of the view that the use of Polythene bags for marketing batlets and capsules of drugs was not ethical and should be stopped. It was recommended that the Drugs Controller (India) may issue a circular also to all the State Drug Controllers for taking further action in the matter.

Item No. 28 : Consideration of the need to issue one licence for different set of premises manufacturing different dosage forms, but situated in the same campus and belonging to the same manufacturer.

The committee was of the view that only one manufacturing licence can be given if the entire management is under one ownership. If the ownership is different of the different manufacturing premises, separate licences would be necessary.

Item No. 29 : Consideration of the need of incorporating the wordings 'Name of the drugs' in the body of Form 26.

It was clarified that Form 26 already requires showing of the names of the drugs to be manufactured, no further action is necessary.

Item No. 30 : Consideration of the need to clarify whether drugs include in IP edition 1955 and deleted from IP (1966) and IP (1985) edition, can be allowed to be manufactured as a Pharmacopoeial drug and labeled as IP '55 in view of the provisions of Rule 124(i) (b).

Since only the immediately proceding edition of the Indian Pharmacopoeia is considered as official under the Second Schedule to the Drugs & Cosmetics Act, any drug which is given in IP '55 could not be considered as pharmacopoeial. However, the manufacturer could show the words 'IP 1955' on the label, if he claims the conformation to these standards.

Item No. 31 : Consideration of the need to authorize the units, in existence since prior to 1981, to set up their own testing facility in a different set of premises, when they are unable to provide laboratory in their existing premises for want of space.

The Committee agreed that it would be in order to permit manufacturers to have their drug testing laboratory in a separate set of premises because of acute housing problem in most of the cities and towns.

Item No. 32 : Consideration of the need to clarify whether Oral Rehydration salt (ORS) having identical composition indicated by WHO but containing

in addition excipents and colour, should be accepted as WHO formula, as claimed by the manufacturers.

It was clarified that oral dehydration salt as per WHO specifications need not contain any colour. The use of colour in oral dehydration salt (ORS) should, however, be discouraged.

Item No. 33 : Consideration of the question as to whether there is infringement of the law by permitting the product to be labeled as 'Ampicillin Sodium for Injection' in a manner prescribed by IP supplement when IP '85 has deleted these words.

It was suggested that the name given for the drug in the latest edition of Indian Pharmacopoeia should be adopted.

Item No. 34 : Manufacture of fixed dose combination of steroids for internal use.

The committee was of the view that since some manufacturers have obtained stay orders for their products, it does not flow from this situation that other manufacturers are free to manufacture the item. The other manufacturers should not be permitted to make these items.

Item No. 35 : Retesting of Drug samples.

The Drugs Controller, M.P. stated that under the Prevenetion of Food Adulteration Act & Rules there is a provision for retesting of food. Dr. Kaul stated that when the State Drug Controller feels that the test report given by the Govt. Analyst is not correct, due to some reason or the other, the State Drug Controller should have power to send the sample for re-testing. Shri Kattishettar however felt that the report of the Govt Analyst could not be doubted by the State Drug Controller. If the Govt. Analyst has given a wrong report, he could be punished under the Civil Servant Conduct Rules. Dr. S. K. Roy, Director, CDL, Calcutta intervening at this stage, said that in such case the same sample could be given to another analyst for re-testing in the laboratory of the Govt. Analyst. The Commissioner Food & Drug Administration, Maharashtra did not support the suggestion and was of the view that in accordance with the provisions of the Drugs & Cosmetics Act, the report of the Govt. Analyst could be checked only by the Director, C.D.L. after testing the same sample and there should not be any deviation from this prescribed procedure.

After detailed discussion it was agreed that there is no need to change the present provisions.

However, it is always open for the State Drugs Controllers to get the same samples tested informally from any Laboratory for his own information.

Item No. 36 : Sub-standard drugs supplied by manufacturers / dealers outside the State – Action to be taken.

The Drugs Controller, Himachal Pradesh, introducting the subject, stated that his State was a purchasing one and all the drugs come from other States. When a drug on test is found to be not of standard quality he refers the matter to the concerned State but unfortunately no action is taken against the manufacturer. The Director Drug Control Administration, Gujarat endorsing the view of the Drugs Cotnroller, Himachal Pradesh stated that when some drugs in the Gujarat State, made by manufacturers in other States, are found to be not of standard quality, he refers these to the concerned States. However, he does not get any reply about the action taken. It would be worthwhile to know what each State is doing in such cases. The Chairman also endorsed these views and informed the Committee that as Drugs Controller (India) when he writes to the States to let him know as to what action has been taken on a drug reported to be not of standard quality many a times he also does not get any reply. It becomes difficult for him to explain to Parliament about the action taken in these individual cases. Shri Kattishettar stated that in most of these cases, he has found that where as the manufacturer should add 100% of the drug in the tablet or capsule, he adds the minimum quantity to make more profits. This is the root cause of such substandard drugs being detected. He suggested that in the new provisions of G.M.P. published for public comments provisions should be made so that manufacturer is required to add 100% of drug. His suggestion was agreed to.

The committee recommended that in all cases of sub-standard drugs matters must be persued to the end and the concerned State Drugs Controller should be informed so that his papers are complete. When the sample has failed action as per the recommendations of the sub-committee of the Drugs Consultative Committee should be taken. If the sample has failed grossly about the content of drug, prosecutions should be launched in the State where the sample was drawn.

Item No. 37 : Assay for ampicillin for oral suspension.

It was recommended that this item may be referred to the Indian Pharmacopoeia Committee for its consideration.

Item No. 38 : Status of Animal feed supplements containing Antibiotics / Antibacterial Vitamins.

It was agreed to bring forward this item in the next meeting of the Drugs Consultative Committee by which time the Drugs Controller, Karnataka will collect more data about the position obtaining in foreign country.

Item No. 39 : Disintegration time for entric coated patent & proprietary medicines – Discrepancy between I.P. specification & Schedule V specifications.

It was recommended that this matter may be referred to the Indian Pharmacopoeia Committee for its consideration.

Item No. 40 : Mechanical Nasal filter to be notified as a drug.

When this item was discussed the Drugs Controller, Delhi Administration stated that now the manufacturer of the item in Delhi has deleted therapeutic claims on the label and has such product is no longer considered as a drug. The item was, therefore, not pressed for consideration.

Item No. 41 : Notification of Medical devices such as IV sets blood transfusion sets and hypodermic medles.

It was explained by the Chairman that the necessary notification in this regard is being processed for publication.

Item No. 42 : Definition of the term "Broad Banding" and its relevance in processing application by Drugs Control Authorities while granting the licence.

Since the subject relates to Price Control of drugs it was felt that it would not be within the ambit of drugs control and was thus not discussed.

Item No. 43 : Containers and delivery systems for eye drops.

The subject was discussed at length and it was observed that the packing of "Eyetone" of M/s. Dey's Medicla Stores had a good packing in a polythene container with good delivery system. The specifications of ths packing could be adopted by others. Shri Amol Chakraborty, Additional Director, Drugs Control, West Bengal promised to get the specifications from the manufacturer and make them available to the Committee. Therafter the other suggestions made in the Drugs Controller, Karnataka was also considered.

Item No. 44 : Water for Injection-Modificaiton of Monograph.

It was recommended that item may be forwarded to the Indian Pharmacopoeia Committee for its consideration.

Item No. 45 : Revision of Licence Fees.

The Chairman stated that the licence fees for manufacture and sale of drugs were raised upwards a few years earlier. However, it is now open to the members to make any suggestions. The members felt tht the licence fees now prescribed were meager and it would be quite reasonable to raise the fees as suggested by the Drugs Controller, Kerala. This view was agreed to and it was recommended that the revised fees as suggested by Drugs Controller, Kerala may be recommended for adoption.

Item No. 46 : Levy of inspection fee under Rule 69(2) and 75(1) of the Drugs and Cosmetics Rules – clarification needed.

It was agreed that there should be inspection fee for each inspection. However, the Chairman suggested that the members may go through this proposal and examine the other connected rules and give their views so that the matter could be processed.

Item No. 47 : Drugs permissible for manufacture by way of repacking – list issued by Drugs Controller (India).

The Committee considered 86 drugs which have been given in the list of drugs which could be permitted for repacking. It was felt that this list may not need any revision immediately. It was also clarified that if a drug manufacturer holding a manufacturing licence in Form 25 desires to repack any drug he need not take repacing licence. However, repacking of drugs given by a manufacturer holding a licence in Form 25, the items to be repacked should be confined to the 86 items.

Item No. 48 : Unhealthy Trends in the manner of labeling.

This subject was earlier discussed and as such no action was considered necessary.

Item No. 49 : Caution legends.

The Chairman stated that generally 'Caution legends' should be given in the form of inserts. However, the inserts should comply to the provisions of the Drugs Magic Remedies (Objectionable Advertisement) Act.

Item No. 50 : Expiry date for bulk drugs.

In regard to the procedure for giving a date of expiry of finished preparations, the Chariman stated that whenever the finished drug is made from a bulk drug which has a shorter date of expiry, it is mandatory that the finished drug cannot have a date of expiry beyond that of bulk drug.

In case the finished product has a number of ingredients, the shortest date of any of the ingredients in bulk form will be the date of expiry.

Item No. 51 : Situation with regard to test for Aids Virus by Blood Banks.

The Chairman stated that a new set of rules for control of blood banks is being processed for replacing the existing one. For AIDS Virus detection, it may not be feasible to test each donor unless such a method is developed and could be easily adopted in our country.

Item No. 52 : Consideration of identifying statutory Testing Lab for the State to ensure quality control or whole human blood IP.

Shri Das, Drugs Controller, Orissa introducing the subject stated that in his State Drugs Inspectors are not able to test blood for Australian antigen because there is difficulty in dispatch of samples for test. This problem would appear to be in two other States and he requested the matter to be discussed.

Dr. Patel stated that each bottle of blood has to be considered as a separate batch. After test the content of blood becomes less and it also becomes useless. Dr. Kaul endorsed these views. In view of these factors the committee came to the conclusion. There is no point in appointing anybody as govt. analyst for bloods. The Chairman stated that the responsibility for testing the blood collected from donors should be on the blood banks who would also carry out test for Australian Antigen.

Item No. 53 : To consider laying down suitable qualification of technical staff incharge of quality control division in Blood Banks.

The Chairman informed the members that as stated earlier, a comprehrensive requirements for blood banks is being processed and would be published for public comments. The draft amendment includes clarification of technical staff incharge of quality control.

Item No. 54 : Review of requirement of testing laboratory in case of units engaged in repacking of drugs and handloom surgical dressings.

The Chairman informed the Committee that since standards for 3 surgical dressings have been recently laid down in the Drugs & Cosmetics Rules, it was deemed expedient to carry out a survey about the standards attained by these surgical dressings. Accordingly, samples were drawn by the Zonal Offices of CDSCO and were sent to the Central Drugs Laboratory for test. According to the reports received majority of the samples had failed.

The committee agreed that since the standards for the three surgical dressings have been laid down recently these should be enforced. No further action at this stage was considered necessary.

Item No. 55 : Prohibition for the manufacture for sale of saccharin containing formulations for paediatric use.

The Drug Controller, Rajasthan, introducing the subject stated that oral rehyderation salt (ORS) marketed by some manufacturers contains Saccharin and this ORS is also used by children. He requested that a ban should be imposed on the use of Saccharin in ORS. He mentioned the name of Fairdeal Corporation which is marketing ORS and this firm has justified the use of Sodium Sacharin in the product "Electrol". Dr. Ashwani Kumar, Dy. Drugs Controller, India, South Zone stated that in Rajasthan a survey was made sometime back and it was found that the ORS of most of leading firms contain Saccharin. It was decided to examine this matter in detail. Also the Indian Pharmacopoeia should have a monograph on ORS.

Item No. 56 : Requirement of minimum are and qualification of competent person for wholesale of drugs.

The Drugs Controller, Rajasthan stated tha the requirements of an area of 10 sq. meter appears to be applicable only for fresh licences. Because at the time of renewal of old wholesale licences, the dealers are saying that the rule does not apply to them.

It was decided to examine this matter in detail.

Item No. 57 : Amendment of Rule 145 (C).

It was agreed that the amendment proposed by the Drugs Controller, Tamil Nadu shall be examined.

Item No. 58 : Amendment to Seciton 18(A).

The Chairman stated that the point raised by the Drugs Controller, Tamil Nadu was considered in depth a number of times but no solution could be found. It is also not possible to amend Section 18(A) at this stage, since piecemeal amendments to the Drugs & Cosmetics Act can not be made. It would be helpful if there is a ruling from the Supreme Court of India about this Section of the Act so that amendment could be made.

Item No. 59 : Amendment to Section 3.

The Chairman informed the committee that gelatine capsules are also used in the Ayurvedic and Unani systems of medicines. No action would appear necessary.

Item No. 60 : Return of records, registers or other documents Section 22 (2A) to be amended.

There was detailed discussion about the implementation of Section 22 (2A) and how some persons are circumventing the enforcement of this Section. Some members also pointed out that this Section runs contrary to the provisions of other Sections of the Act. The Drugs Controller, Tamil Nadu stated that he has also a High Court Judgement which is relevant to this Section. It was decided to examine this matter after the State Drug Controllers have given written notice giving all the points and also after the Drugs Controller, Tamil Nadu has sent a copy of the judgement mentioned by him.

Item No. 61 : Qualifications and experience of staff employed for testing.

This item was discussed earlier and as such no action is necessary.

Item No. 62 : Schedule 'T' to the Drugs and Cosmetics Rules to tbe elaborated.

The subject matter was discussed and it was decided not to make any change in Schedule 'T'.

Item No. 63 : Qualification and experience of staff employed for testing.

The subject was discussed and it was decided not to make any change in the existing rules.

Item No. 64 : Certicate of test or analysis in form 34.

It was considered that the wording of the existing form 34 is clear and it could not be necessary to make any change.

Item No. 65 : Standards for veterinary drugs – Preparation of a National formulary thereof.

The Chairman explained that it has been decided that Indian Pharmacopoeia shall have a separate section for veterinary drugs. It was also not be possible to take any action to control the items like Ajowan, Chirata and Ginger powders. No action was deemed necessary at this stage.

Item No. 66 : Homoeopathic Patent and Proprietary medicine.

The committee recommended that this item may be referred to the Homoeopathic sub-committee of the Drugs Technical Advisory Board.

Item No. 68 : Proposal for amendment of Section 27(b), 27(c) and 27(d) of the Drugs & Cosmetics Act.

The Drugs Controller, Andhra Pradesh, while introducing the subject, stated that although the punishments under the Drugs & Cosmetics Act have been made more stringent, the provisos of Section 27 are being invoked by the Judiciary and there are some cases where the punishment was only I T R O C (Imprisonment till the rising of the Court). He brought to the notice of the Chairman that the Secretary of the Govt. of Andhra Pradesh has written to the the Health Minister in 1986 to take action for deletion of the proviso to this Section. It was agreed to consider this subject in the light of the letter of the Secretary of Andhra Pradesh Government. A copy of this letter has also been received alongwith the agenda item.

Item No. 69 : Compounding of offences under the Drugs & Cosmetics Act.

The Chairman informed the Drugs Controller, A.P. who had raised the subject that the Drugs Consultative Committee at its 24th Meeting had already taken a decision for compounding of offences and further action will be taken.

At this stage Shri C. V. Narasimah Rao, Union Minister for Health and Family Welfare had arrived and the Chairman and the members welcomed him. All the members attending the meeting were introduced to the Union Minister.

The Union Health Minister thereafter addressed the members and a copy of his speech is at Appendixd II. As desired by the Union Health Minister, the State Drugs Controllers explained the steps taken by them to reduce the incidence of substandard and spurious drugs in their States.

How a drug could become substandard was also explained to him. This could be due to various reasons like the failure of tablets in disintegration test, non-compliance of some requirements of standards by surgical dressings, presence of particulate matter in parenteral preparations, etc.

The Chairman explained that the new provisions of Good Manufacturing Practices (GMP), it is expected, will help in reducing many of the defects now found in drugs. The Union Minister of Health expressed his concern

about the presence of spurious drugs in the market and the harm that is caused to the public on use of such drugs. He urged the State Drugs Controllers to take all positive steps for combating and weeding out spurious drugs.

The Union Health Minister also expressed concern about the large number of drug formulations moving in the market. He stated that when there are about 40 to 50 thousand formulations in the country, he is not able to give any satisfactory reply to the Parliament as to how so many products have been licensed. This matter should also be looked into.

The Union Minister of Health stated that many doctors have informed him that the small scale drug manufacturers are giving useless drug to the people. Drugs are for saving life and if there is no quality control assurance, he expressed concern, as to how the patient using such drug would get any medical relief. The Union Health Minister enquired about the cost of setting up a good Testing Laboratory and Dr. S. K. Roy, Director, CDL, Calcutta informed that it would be around Rs.35 lakhs.

The Union Health Minister stated that since there has hardly been any attempt to set up an independent Drug Testing Laboratory, it would be worthwhile to work out if 30 to 40 independent Drug Laboratories could be set up in the country to test all the drugs at random. As a patient he would be interested to know that the drugs taken by him are of standard quality, if it has been tested by an independent laboratory. He requested the Drugs Consultative Committee to think on a long range basis as to how much it will cost to have a such laboratories. If the details could be worked out, he would take further action. The D.C.C. assured him that this matter would be considered seriously by the members and a scheme would be worked out.

The members expressed their gratefulness to the Union Minister of Health & F.W. who had spared his valuable time to discuss the drug control matter in the meeting.

The Chairman and members discussed thereafter the directive given by the Union Health Minister and the question of utilization of private testing laboratories was raised. Most of the members were not in favour of giving any responsive testing work to the private testing labs because of various irregularities and complaints against such labs that have been received.

It was decided that sub-committee with the following composition may be constituted to consider the directives given by the Union Minister of Health & Family Welfare for setting up independent drug testing glaboratories.

The sub-committee for an independent drug testing units :

1. Dr. S.K. Roy, Director, CDL, Calcutt	-	Chairman
2. Dr. M.A. Patel, Director, Drugs Control, Gujarat State.	-	Member
3. Shri Kattishettar, Drug Controller Karnataka.	-	Member
4. Shri Sharma, Commissioner, Food & Drugs Administration, Maharashtra	-	Member
5. Dr. Perumal Drug Controller, Tamil Nadu	-	Member
6. Shri Dubey, Drugs Controller, M.P.	-	Member
7. Dr. P.D.Sethi, Director, CIPL, Ghaziabad.	-	Member
8. Dr. J. L. Kaul, Drugs Controller, Delhi Administration, Delhi.	-	Secretary

It was also decided that this sub-committee may complete its work on priority basis within a period of 3 months.

Item No. 70 : Cognizance of offences under the Drugs & Cosmetics Act – Mandatory sanction to be obtained by the Drugs Inspector.

The Drugs Controller, (M.P.) stated that a provision should be made by which the Drugs Inspector for modern drugs is required to obtain mandatory sanctions from the authority notified by the State Government, as the case for Drugs Inspector for Ayurvedic and Unani drugs. He stated there is a High Court Judgement in this regard. It was agreed to consider this matter further after High Court judgement has been received from him.

Item No. 71 : Availability of drugs in rural areas.

The suggestion of the Drugs Controller, Madhya Pradesh to give exemption to the sale of drugs in villages and area with population of 3 thousand from the requirement of employing a 'qualified person' by the chemist was considered at length. The members were, however, not agreeable to the suggestion as it will conflict with the provisions of the Pharmacy Act. Shri Dubey, however, explained the difficulties for obtaining drugs by the people in the rural areas of Madhya Pradesh

especially in the Baster district. It was agreed that the Drugs Controller, Madhya Pradesh will send a detailed proposal with justification so that it could be considered further.

Item No. 72 : **Consideration of a question, as to whether Transfusion Fluid manufacturers, be allowed to use opaque plastic containers as Govt. Analyst, is not in a position to examine particulate matter in such products in opaque containers.**

It was decided that the question of using opaque plastic containers for transfusion fluids may be referred to the Indian Pharmacopoeia committee so that the manner in which particulate matter could be checked is laid down.

Item No. 73 : **Consideration of a question as to whether product permission for Chloramphenicol Inj. In liquid and powder forms be granted for otherwise.**

Dr. M. A. Patel, introducing the subject, stated that Chloramphenicol Injection in powder form is official in I.P. as well as in U.S.P., while the same in liquid form is official in U.S.P. only. The U.S.P. Monograph for liquid injections clearly states that it is meant for veterinary use only. It is felt that powder form injection should be permitted for human use and another form should be restricted for veterinary use only. It was decided to refer this matter to the Indian Pharmacopoeia Committee.

Item No. 74 :

1. **Section 18 to be amended as mere stocking of drugs is not offence as judiciary does not take a view that it is an offence, State Vs. Mohmed Shabir. Criminal appeal NO. 103 of 1973 (S.C.). It is felt that after the word "Stock" in Section 18 (a), 18(b) and 18(c) a coma is put or amended suitably so as to serve the purpose.**

2. **Section 23(2) of Drugs and Cosmetics Act and Rules thereunder, it is mentioned whom the price tendered under Sub-Section (1) is refused, Drugs Inspector shall tender a receipt therefore in the prescribed form. But when the price is refused for the sample so far no form has been prescribed in the rules. Provisions to be amended suitably. The words "Therefore in the prescribed form" should be deleted.**

3. **Under Rule 15 r/w Section 22 (i) (c) the period in the form 15 may please be extended from 20 days to 45 days.**

4. In Rule 46 : 4th line – After there should be substituted by "the test or analysis should be completed within 30 days or suitable time limit should be fixed for test and analysis.

5. Rule 74(c) : Words "or in any other laboratory approved by L.A." should be deleted since it is inconsistent with Rule 76(4).

7. Rule 74-A(b) is consistant with Rule 71-A(3) and may be suitably.

8. In Rule 79 since there is no provision for rejection applications in Forms 24, 24B, 24A and 27A Instead of "in Form 28 (or F-28B) the words "under this part" should be substituted.

9. In Rule 81 instesad of "in form 28 (or F.28B)" the words " under this part" should be substituted.

10. In Rule 82 instead of "in form 28 (or F28)" the words "under this part" should be substituted.

11. Since there is no provision for rejection of applications in Form 24-C a new sub-rule should be added.

12. Since there is no provision for rejection of application in F.31 or 31-A. After Rule 142-B a new sub-rule should be added.

13. Since there is no provision for rejection of application in F.24 D and 24-E after rule 158-A a new sub-rule should eb added to that effect. Similar provision as in rule 79, 81 and 82 of inspection before grant of licence should be introduced.

14. Provisions similar to Rule 65-A should be made applicable to all drug and cosmetics manufacturing license and a provision i.e. "the application for the grant of a licene or any person granted a licence under this part shall on demand, furnish to the L.A., before the grant of licence or during the period the licence is in force as the case may be, documentary evidence in respect of the ownership or occupation rental or other basis of the premises, specified in the application for licence or in the licence granted, constitution of the firm or any other relevant matter, which may be required for the purpose of verifying the correctness of the statements made by the applicant or the licence while applying for or after obtaining the licence as the case may be" inserted.

15. Since there is no provision to control the use of R.M. used for drugs or cosmetics which are found to be not of standard quality by the manufacturer. Following amendments parallel to those for approved

testing laboratory should be made. After Rule 74(n), 74-A(h), 74-B(5), 78(o), 78-A(6) "In case any raw material of drug is found on test to be not of standard quality, the licensee shall furnish the Licensing Authority with a copy of the test report on such raw material with the protocols of test applied."

16. **After Rules 142 (f), 142-B(f)**

"In case any raw material of a cosmetics is found on test to be not of standard quality, the licensee shall furnish the Licensing Authority with a copy of the test report on such raw material with the protocols of test applied."

Since all the above proposals of Food & Drugs Administration Maharashtra related to specific amendments of the Drugs & Cosmetics Act and Rules, it was decided to examine them individually and take necessary action.

On the suggestion the of the Commissioner, Food & Drugs Administration, Maharashtra it was also recommended to take action on the following points :

(a) A proforma may be prescribed when the price tendered for a sample drawn by a drug inspector is refused.

(b) Secondly changes may be done in the Rules which require that each manufacture shall have its own testing laboratory. This is necessary because of the Stay Order granted by the Bombay High Court in the Writ Petition filed by manufacturers who do not have their own testing laboratory.

Item No. 75 : **Instead of current system of Biological and non-Biological licences for manufacturing licence following licensing provisions are to be made for manufacturing of drugs. This will offer a definite advantage over the present system and bring a uniformity among licensing of all the discipline of drugs :**

(a) Manufacturer's licence :
(b) Product licence :

The suggestion was considered and it was felt that the present system of licensing was in force for a long time and it would be difficult to introduce another "product licence".

Item No. 76 : ANY OTHER ITEM WITH THE APPROVAL OF THE CHAIR.

The Drugs Controller, Goa stated that the Govt. Analysts and the private laboratories do not do all the tests for a drug and declare the product as of standard quality. Dr. S. K. Roy, Director, CDL stated that this subject will be discussed in the next Govt. Analysts' Conference.

The Drugs Controller, Andaman stated that in the group of Island in his Union Tertitory there are no qualified person for chemist shops and exemption may be given under Rule 65(15) of the Drugs & Cosmetics Rules. The Chairman requested him to write to the Drugs Controller, India so that the matter could be examined.

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

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