MINUTES OF THE 24TH MEETING OF THE DRUGS CONSULTATIVE COMMITTEE HELD AT NEW DELHI ON THE 8TH & 9TH JANUARY, 1985

The Chairman welcomed all the members present in the meeting and informed that the meeting is being held after a lapse of nearly 2 years although in 1983 a special meeting was held for discussing the action to be taken consequent on the amendment of the Drugs and Cosmetics Act 1982. Although a meeting of the Drugs Consultative Committee was not held in 1984, a meeting of the State Health Ministers' was held in 1984 to discuss problems relating to Drugs Standard Control and Prevention of Food Adulteration.

The Chairman stated that as the Seventh Five Year Plan would be launched from 1st April, 1985 and all the State Drugs Controllers would have made provisions in their State Plans for expansion of the State Drugs Control Machinery. So far as the Central Plan for Drugs Control is concerned, the Chairman stated that we had tried to make a provision for assisting the States for strengthening their Drug Inspectorate machinery as well as providing financial assistance for procurement of sophisticated drugs testing equipment. If the Planning Commission accepts these proposals, the Central Government may be able to extend to State Drug Controllers some assistance in strengthening the Drugs Control Administration. The Chairman pointed out that whatever central assistance the Central Government can give could only be supplementary and it would be necessary for the State Government to provide adequate financial resources for strengthening the State Drug Control Organisations during the Seventh Five Year Plan.

The Chairman appreciated the work done by the members of the Sub-Committees constituted by the last Drugs Consultative Committee and thanked the Chairman and members for the excellent word done by them in preparing the reports of the Sub-Committees on time for consideration of the Drugs Consultative Committee.

The Chairman then requested all the State Drugs Controllers present, to give in brief, an account of the proposals they have in the Seventh Five Year Plan for augmentation of the Drug Control Machinery, their testing facilities, Intelligence cum Legal Wing, etc. The State Drugs Controllers in turn informed the Committee of the various provisions they have made in the Sate Seventh Five Year Plan. The State Drugs Controllers requested the Chairman to support their proposals when these State Plans are discussed by the Planning Commission. The Chairman assured them of his support. He informed the State Drugs Controllers to ensure that the provisions that has been accepted by the Planning Commission should be utilized for the strengthening of the Drugs Control Administration and should not be diverted to any other programme.

Items of the agenda were then taken up for consideration.

Item No. 1 : The minutes were confirmed with no change.

Item No. 2 : The Chairman stated that the action taken on the recommendations made at the last meeting of the Drugs Consultative Committee was set out in Annexure I and members could seek clarifications and make observations on any point given in the statement. As none of the members had any observations to make, the action taken was noted.

Item No. 3 : **(a) Guidelines regarding action to be taken in respect of samples found to be not of standard quality.**

The suggestion made by the Commissioner, Food and Drugs Administration, Maharashtra State, Bombay regarding change in the guidelines about action to be taken in respect of samples found to be not of standard quality was discussed and the Committee decided not to make any changes in the guidelines already issued.

(b) Manufacture of Cephalosperine antibiotics.

The general consensus of the Committee was that the Cephalosporine preparations should be manufactured in separate premises to the extent possible. Where it is not feasible, Cephalosporine may be permitted to be manufactured in premises used for the manufacture of antibiotics other than penicillin.

Item No. 4 : Reports of Sub-Committee.

The following reports submitted by the Sub-Committees appointed by the Drugs Consultative Committee were presented at the meeting and the Chairman suggested that since there was not enough time for the Drugs Controllers to go through the reports and give their comments, they may do so within a period of 2 months from the date of the Drugs Consultative Committee meeting. The reports of the Sub-Committee would be finalized by the Chairman in light of the comments received.

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 courses outlined by the earlier Sub-Committee.

ii) Report of the Sub-Committee to permit one testing laboratory for testing the drugs manufactured by a group of manufacturers.

iii) Report of the Sub-Committee to lay down details of space, equipment, etc. for the manufacture of cosmetics.

iv) Report of the Sub-Committee on licensing under the Drugs and Cosmetics Rules for manufacture of diagnostic reagents.

v) Report of the Sub-Committee to got into the details of manufacture of surgical dressings and to suggest minimum hygienic conditions required for the manufacture of surgical dressings / bandages.

Item No. 5 : Establishment of a formulation bank at the Central level.

The suggestion to establish a comprehensive list of all formulations licensed for manufacture at the Central level at Headquarters can be considered only if the State Drug Controllers can furnish to the Drug Controller (India) the list of drug formulations licensed by them in their States. As all the State Drugs Controllers are not in a position to do so this may not be possible for the present.

Item No. 6 : Control over Medical Devices.

The Committee accepted the report of the Sub-Committee and on the basis of the report of the Sub-Committee and the specifications drawn by them the Committee decided to recommend control of the following devices under the Drugs and Cosmetics Act.

1. Disposable Perfusion Sets.
2. Disposable Hyperdermic Syringe.

3. Disposable Hyperdermic Needle.

The question whether the above medical devices could be notified as "Drugs" in absence of standards was considered.

It was felt that if these devices are notified as drugs, the State Drug Control Authorities may find it difficult to exercise any control in absence of any standards or rules. It was, therefore, decided that the standards for these devices alongwith the rules shall be incorporated in the Drugs and Cosmetics Rules before they are notified as drug.

Item No. 7 : Grant of permission to manufacture "Shingar Sindoor" as a Cosmetic under Cosmetic Manufacturing Licence.

The Director, Food & Drugs Control Administration, Gujarat stated that 'Shingar Sindoor" manufactured in his State as a Cosmetic contains 90.90 % Dolomite while the dictionary meaning of the word Sindoor is Red Lead. The Committee was of the view that the present practice of permitting such products as Singar Sindoor to be marketed as cosmetics may continue.

Item No. 8 : Manufacture and marketing of Water for Injection in vials of 5 ml. 10ml. 25 ml. etc.

The Committee decided that Water for injection should not be allowed to be marketed in vials even with a bacteriostatic.

Item No. 9 : Printing of design of fruits on the label and carton on drugs – misbranding.

It was pointed out to the Committee that the Commissioner, Food and Drugs Administration, Maharashtra had prosecuted a firm for contravention of Section 17(C). It was decided that the details of the case and the outcome of the prosecution may be obtained from him before a final decision is taken.

Item No. 10 : Drug marketing and retail sale of medicinal products.

The Committee observed that there is no provision under the Drugs and Cosmetics Rules that all injections should bear the date of expiry. The drugs covered by Schedule 'P' are required to give the date of expiry as stated in that Schedule. The Drug Rules are however, being amended to require a maximum life period of 5 years to be given on the labels of all drugs. The Committee decided that a plastic spoon should be supplied with liquid preparation of antibiotics and chemotherapeutic drugs for ensuring proper dosage.

Item No. 11 : Compounding of offences.

The Chairman stated that as the Drugs and Cosmetics Act has been amended only recently a provision in the Act for compounding of offences can be considered only when the Act is amended in future.

Item No. 12 : Colour code for various ophthalmic drugs and labeling these drugs with symbol of eye.

The Committee was of the view that it is not practical to have symbolic pictures in colour code for various paediatric ophthalmic preparations.

Item No. 13 : Consideration of the question whether a cosmetic with the same brand name can be marketed by two different cosmetic manufacturers.

Dr. Kaul, Deputy Drugs Controller, Delhi Administration, stated that he has forwarded to the Drugs Controller (India) the legal opinion received by him regarding the manufacture of a cosmetic with same brand name by different manufacturer under agreement which is contrary to the opinion given by the Ministry of Law. It was decided to refer the matter again to the Ministry of Law for advice.

Item No. 14 : Classificaiton of Syrups, Tooth Powder, Hair Oils and Tooth Paste, etc. vis-à-vis the definition of "Ayurvedic and Unani Patent or Proprietary Medicine."

The Committee decided that if the manufacturer claims the product manufactured by him as an Ayurvedic medicine then the product may be licensed as an Ayurvedic medicine under the provisions of Drugs and Cosmetics Rules, otherwise it may be considered as a Cosmetic.

Item No. 15 : Retention of control samples by the approved testing laboratories.

The proposal of retention of control sample by the approved testing laboratories for a specified period was considered but was not agreed to.

Item No. 16 : Manufacture of preparations containing Insoluble Bismuth Salts :

The Chairman informed the State Drugs Controllers that the advice given to them to ban the manufacture of the preparations containing insoluble Bismuth Salts was prior to the amendment of the Drugs and Cosmetics Act in 1982. The Bombay High Court has ruled that such directives are not legally valid.

Now that the Central Government has acquired powers to prohibit the manufacture or sale of a drug it would be desirable to take action only on basis of Notification issued by the Central Government since only such action would be legally valid.

Item No. 17 : Disclosure of the name of the manufacturer to the Government Analyst when a sample is sent for analysis.

It was stated that Form 18 does not specifically require the name of the manufacturer to be given to the Government Analyst when a sample is sent to him for analysis. The Committee, after detailed discussion felt that giving of the name of the manufacturer may prejudice the Government Analyst and Status Quo may be maintained.

Item No. 18 : Declaration of EMPTY GELATIN CAPSULES as Drugs – Certain clarifications :

As Empty Gelatin Capsules have been brought within the purview of the definition of the term drug in the Drugs and Cosmetics Act as amended in 1982, a licence for the manufacture and sale of Empty Gelatin Capsules is necessary. As regards the labeling of the capsules the requirements laid down in Rule 96 of the Drugs and Cosmetics Rules would apply. So far as the colours used in the manufacture of capsules are concerned, it was agreed that the container of the capsules need not indicate the specific approved colour that has been used. It should, however, be indicated on the container that approved colours have been added.

As regards the standards of these Empty Gelatin Capsules, it was decided to constitute a sub-committee with the following members to workout standards for Empty Gelatin Capsules.

1.	Dr. M. A. Patel, Director, Food and Drugs Admn., Gujarat State.	Chairman
2.	Dr. J. L. Kaul, Dy. Drugs Controller, Delhi Adminstration.	Member
3.	Shri S. D. Bhirud, Commissioner, Food & Drugs Admn., Maharashtra State.	Member
4.	Dr. P. K. Gupta,	Member (Convenor)

Dy. Drugs Controller,
South Zone,
Madras.

To a query as to whether Empty Gelatin Capsules can be sold to an Ayurvedic manufacturer, the Chairman clarified that there was no objection to such capsules being sold to the licensed Ayurvedic manufacturers.

Item No. 19 : Standards to be followed for certain conventional types of Tooth Powders.

The Chairman enquired from the members as to whether Tooth Powder containing "burnt husk" as an ingredient had been tested for ISI specifications and found not to comply with it. Unless this is done, it would not be possible to approach the ISI for modification of their specifications to cover such Tooth Powders. It was decided that the State Drugs Controllers should collect information regarding the specifications of Tooth Powder containing "burnt husk" and forward them to the Directorate to enable the matter being taken up with the ISI.

Item No. 20 : Joint Inspection Programme of Blood Banks.

It was decided that the State Drugs Control Authorities should furnish a list of blood banks licensed by them in their respective States to the Zonal Offices and chalkout a joint inspection programme for inspection of blood banks in consultation with the concerned zonal offices, such programme should cover inspection at the time of granting or renewal of licences.

Item No. 21 : Sale of Homoeopathic Drugs.

The Chairman stated that prices of homoeopathic medicines are not controlled under the Drugs Price Control Order. As regards the sale of homoeopathic medicines manufactured in U.P. without a manufacturing licence number the Food and Drugs Controller U.P. clarified that in U.P. licences for manufacture and sale of Homoeopathic medicines are now being granted. It was also decided that wherever any difference in respect of products manufactured in a State comes to notice the matter should be taken up with the State Drugs Controller concerned.

Item No. 22 : Manufacturing / Sale of diagnostic reagents.

The question of manufacturing / sale of diagnostic reagents has already been discussed vide item No. 4(iv).

Item No. 23 : Inclusion of toilet soap in the cosmetics definition.

The Chairman informed that recently the Drugs and Cosmetics Act has been amended to widen the definition of cosmetics to include toilet soaps. He stated that both existing manufacturing unit of toilet soap and the new units coming up for this purpose should also be licensed and necessary instructions have been issued to the State Drug Control Authorities on testing of raw materials and giving Batch No. so far as toilet soaps are concerned.

Item No. 24 : Consideration of the question of invoking section 26A, for any product, which is declared as irrational combination and is likely to involve risk to human beings.

The Chairman stated that combinations of Ethambutol Hydrochloride and Isoniazid has been considered as an irrational combination and should not be allowed to be manufactured. As some State Drugs Control authorities have permitted manufacturing of such combination, the matter will be examined again in consultation with the medical experts and further action will be taken.

Item No. 25 : Consideration of the question of framing Rules for repacking of Cosmetics.

The Committee agreed that repacking of cosmetics may be considered as a manufacturing activity and a regular manufacturing licence may be given for repacking cosmetic.

Item No. 26 : Repacking of condoms.

The Committee unanimously agreed that a regular licence in Form 25 should be given for repacking of condoms. During the discussion on repacking of items in general, the Chairman clarified that only 86 items earlier agreed by the Drugs Consultative Committee for repacking should only be permitted to be repacked and in case of any other item regular manufacturing licence may be insisted upon under the provisions of Drugs and Cosmetics Act.

Item No. 27 : Consideration of the question of testing the product as B.P. when the label claim is BPC.

The Committee agreed that a product permitted to be manufactured as BPC and labeled as BPC should be tested by the Government Analyst as per requirements of BPC. If, however, the same product is subsequently included in B.P., the Government Analyst should intimate accordingly to

the concerned State Drugs Controller by a separate note in the report so that the manufacturer could be advised to comply with the specification.

Item No. 28 : Consideration of the question of permitting the use of "Logo" of a firm embossed on the label / carton / cap of the bottle, when they are not the actual or true manufacturers.

The Chairman stated that the question of permitting the use of "Logo" of a firm by its sister concern may be referred to the State Legal Department by the State Drugs Control Authorities and action may be taken in the light of the advice given by the Legal Department.

Item No. 29 : Consideration of the question to make it obligatory to the manufacturers and repackers to indicate on the label of the product the date of manufacture / date of repacking.

The Chairman explained that Schedule 'P' of the Drugs and Cosmetics Rules is being revised which would require all drugs to be labeled with date of expiry which will be for a maximum period of five years. It was further clarified that repacking is considered as a manufacturing activity.

Item No. 30 : Consideration of the question as to whether pharmacopoeial preparations marketed either under a pharmacopoeial name or a trade name can claim the same as a pharmacopoeial preparations when the strength of the preparation is not the usual strength mentioned in the pharmacopoeia.

The Committee was of the view that if the preparation is included in the I.P. whatever strength it is being marketed, will be considered as I.P.

Item No. 31 : Consideration of the question of whether deodorants and cleansers showing Rideal Walker Coefficient should be treated as disinfectants.

The Committee was of the view that if a product is labeled and marketed only as a deodorant no licence is required under the Drugs and Cosmetics Rules.

Item No. 32 : Consideration of the question of whether ESI-Medical Stores should obtain a drug selling licence for the distribution of drugs to their own patients.

The Chairman stated that even the Government Medical Stores have been licensed for distributing drugs and hence ESI Medical Stores should also be licenced for the distribution of drugs to their own patients under the provisions of Drugs and Cosmetics Act.

Item No. 33 : Consideration of the question of whether preparation containing a single vitamin alongwith other ingredients such as Calcium salts should be treated as preparation containing a single vitamin only for the purpose of exemption from the provisions of Schedule V.

The Chairman stated that preparations containing single vitamin along with other ingredients will not be covered by the requirement of Schedule "V".

Item No. 34 : Use of second hand bottles for manufacture of transfusion.

The Committee discussed at length the question of re-using USP Type II Bottles in the manufacture of transfusion fluids and reiterated their earlier decision that Type-II Bottles should not be permitted to be re-used. The Chairman stated that in some of the States directives have been given by the State Government to their hospitals to destroy the bottles after use. Some of the members pointed out that if empty bottles ought to be destroyed by the hospitals audit objections may be raised. The Chairman stated that if these empty bottles are auctioned by the hospitals they would be re-used for manufacture of transfusion fluids. The Chairman was of the opinion that as the pharmacopoeia does not permit the re-use of Type-II Bottles, strict control should be kept on the manufacturers who sell the transfusion bottles at a very cheap rate as they may be re-using Type-II bottles. He further reiterated that as the problem of re-use of bottles is faced by many States, he would take up the matter with the Ministry of Health and Family Welfare requesting them to write to the State Governments to advise the hospitals in their States not to auction Type-II Bottles and to destroy them.

On the point raised by some members regarding re-use of vials by hospitals, the Chairman stated that the vials also should not be auctioned but should be destroyed. In any case the re-use of vials by hospitals or by any individual manufacturer should never be permitted.

Item No. 35 : Provision of testing facilities.

The Chairman stated that standards for surgical dressings namely; bandage, absorbent qauze and plaster of paris bandage have been laid down under the Drugs and Cosmetics Rules and the manufacturer of surgical dressings will have to comply with these standards. As there are not many tests to be performed, these manufacturers should have their own testing facilities but the manufacturing chemist may be permitted as a special case to do the testing also. The Chairman further stated that the State Drugs Control authorities should use their discretion in such cases taking into consideration the genuine difficulties experienced by the manufacturers.

Item No. 36 : Cosmetic preparations.

The Chairman explained that there are no standard books available wherein formulae of the cosmetics preparations are given. Each manufacturer has his own formulae. The ISI has however, drawn up specifications for some cosmetics which are now statutory. The Chairman requested the members to send their observations regarding the enforcement of ISI standards for 11 finished cosmetics which have been laid down under the Drugs and Cosmetics Rules.

Item No. 37 : Issue of licence for Blood Bank.

The Chairman stated that detailed guidelines for Blood Banks have been prepared and action has been taken to incorporate them in the Drugs and Cosmetics Rules. It was decided that all Blood Banks including Nursing Homes collecting blood for supply to their patients should also be licenced under the provisions of Drugs and Cosmetics Act and Rules.

Item No. 38 : Approval of Vitamin B Group preparations Vitamin B Complex.

After detailed discussion the Committee agreed that the preparation containing vitamins if labeled as "Vitamin B Complex", should contain all the 5 vitamins of Vitamin B Group, namely; Vitamin B_1, B_2, B_6 Niacinamide and Calcium Panthothenate.

Item No. 39 : Consideration of question as to whether licence of cosmetics manufacturer who is having competent technical staff approved previously prior to Drugs and Cosmetics (Second Amendment) Rules, 1945 by the Licensing Authority on the basis of experience and training should be renewed or they should be insisted to have competent technical staff having qualification as laid down in Rule 139 of Drugs and Cosmetics Rules, 1945.

The Chairman stated that according to the amended provisions of the Drugs and Cosmetics Rules, before a licence in Form 32 is granted or renewed the applicant should have a competent technical staff for supervison of manufacturing all cosmetics. The Committee, however, decided that the persons already approved for the manufacture of the same categories of cosmetics may be continued to be approved. In case of new applicants and for additional categories, however, qualified persons should be insisted.

Item No. 40 : Consideration of question of amending Rule 62 of Drugs and Cosmetics Rules, 1945.

It was stated that in Rule 62, the word "distribute" is not there and hence it creates doubt as to whether a separate licence is required for each place if drugs are only to be distributed at more than one place. It was agreed to amend Rule 62 of the Drugs and Cosmetics Rules to cover distribution also.

Item No. 41 : Amendment of Form 20-B and 21B.

The proposal of amendment of Form 20 B and 21 B to include the name of competent person as laid down in Rule 64(2) of Drugs and Cosmetics Rules, 1945 has been approved by the Drugs Technical Advisory Board. Further action is being taken in the matter.

Item No. 42 : Clarification on clause 5-A of Schedule K.

It was decided to examine the scope of clause 5A of Schedule 'K' to decide which institutions/Nursing Homes should be exempted from the provisions of taking a retail sale licence.

Item No. 43 : Stocking of date expired drug by Registered Medical Practitioners / Hospitals.

It was pointed out that there is no provision under clause 5A or clause 5B of Schedule 'K' for prohibiting the stocking or distribution of date expired drugs by Registered Medical Practitioners, Hospitals, etc. The Chairman stated that the matter will be examined and if necessary suitable amendments if Schedule 'K' will be provided.

Item No. 44 : Discussion regarding 17B(a) spurious drugs manufactured under a name which belongs to another drug.

The Chairman pointed out that even the State Drugs Control authorities do not have consolidated list of products licensed by them for manufacture in the State. It will not be possible to furnish information on this subject to other States. He, however, advised the State Drugs Control authorities to check brand name of the product in the Indian Pharmaceutical Guide before licensing in their States. He, however, stated that the practice followed by the Delhi Administration in taking an Affidavit from the manufacturer to the effect that "to the best of their knowledge the product is not marketed in the country and does not contravene the trade mark of another manufacturer" could be considered by other State Drugs Control authorities, in consultation with their Law Department.

Item No. 45 : Discuss about printing of minutes of the D.C.C. and make it available to all Drugs Control Authorities of the State.

On the point raised by some State Drugs Controllers regarding the printing of the minutes of the Drugs Consultative Committee, the Chairman agreed that the minutes of every 10 meeting of the Drugs Consultative Committee may be printed. Necessary ation will be initiated in this regard.

Item No. 46 : Report of standard quality, should be made known to the concerned Drug Controller.

The question of circulating complete information about analytical reports of all the samples declared to be of standard quality by the Government Analyst to the concerned State Drugs Control Authorities where the manufacturers are situtated, was discussed at length. The members unanimously agreed that such information will definitely be useful for them to monitor the overall quality status of drugs manufactured by firms in their States, but felt that it would not be feasible to give this information considering the voluminous work involved in it.

Item No. 47 : Blood Banks.

The Chairman agreed that a training programme for about a week will be formulated for Drugs Inspectors regarding inspection of Blood Banks in the training programme conducted by Deputy Drugs Controller (India), West Zone, Bombay under the Drugs Inspectors Training Schem.

Item No. 48 : Amendment of Section 19(3) (a) of the Drugs and Cosmetics Act.

The Chairman stated that the amendment of Section 19(3)(a) of the Drugs and Cosmetics Act will be considered when the Act is amended in future.

Item No. 49 : Amendment to Rule 85 of the Drugs and Cosmetics Rules.

The Committee decided that it is not necessary to amend Rule 85 of the Drugs and Cosmetics Rules empowering the licensing authority to delete the product permitted for manufacture, such as banned drugs, drugs declared not of standard quality, etc.

Item No. 50 : Provisions of Rule 65 (11-A).

The Chairman explained that at present the Chemists are prohibited from supply substitute of a drug, included in Shedule H and X, prescribed by a Registered Medical Practitioner. He, however, felt that it would not be desirable to extend this prohibition to all the drugs.

Item No. 51 : Amendment of Rule 124A.

The Chairman stated that necessary amendment to Rule 124 (a) to replace the wordsn "British Vaterinary Codex" by the words "British Pharmacopoeia Vaterinary" would be carried out.

Item No. 52 : The 2nd proviso in rule 64 under which area and qualification of competent person have been prescribed may kindly be discussed.

The Committee decided that the prescribed area of 10 SQ meters may be insisted in cas of only new applicants for wholesale licensing and in case of wholesalers who are already licenced by the Drugs Controller this requirement need not be insisted upon. The Chairman stated that a rule is being introduced that the name of the competent person in charge in case of a wholesale licence shall have to be given in the licence.

Item No. 53 : Consideration regarding 3rd pilot tube to be provided by the Blood Banks with the citrated blood bottles.

The Chairman stated that the Blood Banks may be asked to spell out difficulties experienced by them in view of the instructions issued by this Directorate to provide 3rd pilot tube with the citrated blood bottles so that further action can be taken in the matter.

Item No. 54 : Sub-standard Test Reports – action thereon.

It was decided that whenever a sample of a drug, manufactured in another State, is found to be sub-standard, the State Drugs Controller of the State where the sample is found to be sub-standard should give to the State Drugs Controllers where the drug is manufactured detailed information linking the sale of the product in his State to the manufacturer in the another State.

Item No. 55 : Statement regarding action taken on drugs found to be not of standard quality.

The Chairman explained a proforma was prepared and sent to all the State Drugs Controllers to obtain information regarding details of action taken on drugs found to be not of standard quality for every quarter and requested the State Drugs Control authorities to furnish the required information in time to him.

Item No. 56 : Review of decision taken in 21st D.C.C. meeting regarding formulation in tablets form official in Pharmacopoeia.

The Committee decided that the formulations official in the form of tablets may also be permitted to be manufactured in the form of capsules.

However, the capsules should not be permitted to be labeled as I.P. if hey are not official in I.P.

Item No. 57 : Permission to repack dual purpose item like sodium bicarbonate, Glycerin, Boric Acid in specifications other than I.P.

The Chairman stated that I.P. specifications of the dual purpose items are being revised. He further clarified that if a dual purpose item does not conform to I.P. specifications, it may be permitted to be manufactured with specifications of other pharmacopoeias.

Item No. 58 : Use of raw materials.

On the point raised by some members regarding purchase of raw materials from licenced dealers for making formulations, the Committee decided that the manufacturers under the provisions of Drgus and Cosmetics Act and Rules thereunder must purchase raw materials required by them for making formulation only from licenced dealers.

Item No. 59 : New Drug.

The Chairman pointed out that it has come to his notice that different State Drug Control Authorities sometime interpret differently on the meaning of the term "New Drug" notwithstanding the explanation of the term "New Drug" that is given under Rule 30A of the Drugs and Cosmetics Rules. The members also felt that there is no uniformity in granting permission for new drug formulations by the various State Drug Control Authorities.

The Chairman stated that although permission to import or manufacture any new drug is required to be obtained from the Drugs Controller (India), instances have come to notice where certain single ingredient new drug or "New combinations" not yet approved by the Drgus Controller (India), have been licensed by some State Drug Control Authorities. This often creates a peculiar situation where an application of a particular drug is pending with the Drugs Controller (India) for clearance, the same drug has been licensed to be marketed by some State Drug Control Authorities.

A concern was expressed by the members that necessary guidelines should be framed as to what would be covered by the term "New Drug". It was decided that a Sub-Committee should be constituted to go into the matter in depth under the Chairmanship of Professor J. Das, Director of Drugs Control, West Bengal. The other members of the Committee are :-

1. Shri S. D. Bhirud, Member
   Food & Drugs Administration,

	MAHARASHTRA STATE, Bombay.	
2.	Shri S. S. Kattishettar, Drugs Controller, KARNATAKA, Bangalore.	Member
3.	Dr. Gyan Prakash, Drugs Controller & Director, RAJASTHAN, Jaipur.	Member
4.	Dr. M. A. Patel, Director, Food & Drug Control, Administration, GUJARAT STATE, Ahmedabad.	Member
5.	Dr. V. Perumal, Drugs Controller, TAMILNADU, Madras.	Member
6.	Dr. P. Das Gupta, Dy. Drugs Controller (India), Dte. General of Health Services, Nirman Bhawan, New Delhi.	Member Secretary

Dr. Kannan, Deputy Drugs Controller (India), drew the attention of the members to the following matters :-

1. Replies to the telegrams and letters sent by this Directorate on Parliament Questions should be sent expeditiously to enable the Directorate to furnish the information to the Parliament. In case of the assurances given to the Parliament Dr. Kannan requested that information should be given to this Directorate as early as possible so that the request for extension of time for fulfillment of these assurances is avoided.

2. The State Drugs Controllers should sent the list of the names of the manufacturers of Allopathic, Ayurvedic, Homoeopathic and Unani Medicine and Cosmetics upto the end of December 1984 by the end of April, 1985 so that this list could be consolidated at the Centre and could be sent to all the state Drugs Controllers. He further requested that 100 copies of these lists may be given to us within the stipulated period.

3. The State Drugs Controllers should furnish in time their quarterly / half yearly and annual reports in accordance with the proforma which have been circulated. This has been emphasized by the Estimates Committee of Parliament and should be complied with.

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

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