MINUTES OF THE 22ND MEETING OF THE DRUGS CONSULTATIVE COMMITTEE HELD AT NEW DELHI ON THE 9th & 10TH JULY, 1981

The Chairman welcomed all the members present at the twenty second meeting of the Drugs Consultative Committee. He said that the Committee was meeting after 18 months, as the meeting could not be convened in 1980. He further said that due to Parliament and other official preoccupations the meeting could not be held earlier and hoped that every effort would be made in future to hold the meeting at least once every year if not more frequently.

The Chairman expressed great regret and sorrow over the sad demise of Shri C. Raghavendra Rao, I.P.S., Drugs Controller of Andhra Pradesh, who was a member of the Drugs Consultative Committee. He stated that Shri Rao, had contributed significantly to the deliberations of this Committee and had actively participated in preparing the Manual for guidance of Drugs Inspectors and Senior Supervisory Officers. The Committee observed at two minutes silence in the memory of the departed soul. It was agreed that a suitable condolence message will be sent on behalf of the Committee to the bereaved family. The Chairman made the following salient points in his opening remarks :-

(1) The Subject of enforcement of the Drugs and Cosmetics Act was an item for discussion at the last meeting of the Central Council of Health which was held in New Delhi from 15th to 17th June, 1981. The Council has in a resolution recommended that the decisions taken by the Drugs Consultative Committee, which is a statutory Committee under the Drugs & Cosmetics Act, should be uniformally implemented by all the States. This recommendation is important as it lends support from the highest body so far as health is concerned to the decisions which would be taken in this meeting. The State Drugs Control authorities should take advantage of the recommendations of the Central Council of Health in strengthening and streamlining the drug control machinery.

(2) The subject of "drug adulteration" is a matter of concern to all. There is frequent criticism from the Parliament and legislatures as well as from the public regarding the

prevalence of sub-standard and spurious drugs in the country. This criticism has to be faced by spelling out the action that has been taken in tackling this problem.

(3) The need to exercise a stricter control at the time of licensing of new undertakings and the renewal of licences of existing units was reiterated. It should be ensured that only units with adequate facilities and competence are licensed and extreme care should be taken in licensing of products for manufacture. When a new product has been licensed for manufacture, the manufacturers should be required to supply protocols of test in respect of the few batches. The sampling programme should be directed towards such products and a high priority should be given in the sampling and testing of new products introduced into the country.

(4) On the recommendations of the Vaccine Control Board a letter has been issued to all the State Drugs Control authorities requesting them that the samples of vaccine from manufacturing units in their States should be sent to the Central Research Institute, kasauli for test and a six monthly report be sent regarding the results of tests. Necessary action may be taken in this regard.

(5) The joint inspection should be carried out by Central and State Drugs Inspectors not only at the time of licensing of approved laboratories but also at the time of renewal. This provision of joint inspection before licensing has been introduced on the specific recommendation of the Drugs Technical Advisory Board which had felt that as products would be released to the consumer onteh basis of the reports of the approved laboratory a joint inspection was desired.

(6) The problem of spurious drugs attracts vide publicity and often figures in Parliament Questions and State legislatures. It is a disturbing development that the number of prosecutions launched for the manufacture and sale of spurious drugs has shown a sharp decline. Though this could be taken to indicates hat the problem of spurious drugs is on the decline, it is seem from the report received that it is not so. Spurious drugs are moving in the market and unless a vigorous effort is carried out to find out the sources from where these originate, they would continue to move in the market. Even the few samples that have been drawn by the watchers in the Zonal Offices have shown the presence of spurious drugs. Intensive surveys should be carried out to ascertain the prevalence of spurious drugs.

(7) The problem of manufacture of imitation products is at present confined to a few States and this has be on brought to the notice of the concerned State Drugs Control authorities, who have taken some action in the matter. Imitation products constitute a fraud on the consumer particularly the illiterate or partially literate and it should be ensured that such products are not manufactured in the country and stringent action such as prosecution should be taken against such manufacturers.

The Chairman stated that it was brought to his notice that the procedure circulated earlier in respect of reports of adverse / fatal reactions of Penicillin preparations is not

being followed by some State Drugs Control authorities. He agreed to recirculate the procedure for information of the members.

The Chairman observed that from the information collected of the action taken on the sub-standard reports, in many cases only a warning is issued to the manufacturer even though more samples of the same manufacturer are found as sub-standard. He stated that some guidelines of the action taken in such cases would have to be evolved. He requested the State Drugs Control authorities to take action in respect of all sub-standard reports. Prosecutions should be launched in cases where the State Drugs Controllers find that a large number products of the company have been found sub-standard; whenever Zonal Officers request for joint inspection; State Drugs Control authorities should respond immediately and extend the necessary co-operation.

The Chairman requested the State Drug Controllers to keep the Zonal Officers informed whenever new licensees are issued in their States.

The Chairman expressed his appreciation to the Chairman and members of the various sub-committees for the labour they had put in and for timely submission of their reports.

Referring to the opening remarks of the Chairman Shri Sane informed that Maharashtra State has passed an ordiance to control the activities of slum lords, boot leggers and drug offenders, which is effective from 14th April, 1981. He stated that in Maharashtra there is consumer education plan (or programme) through the media of local papers, slides, posters, brochures and especially by Bombay Doordarshan who use Food & Drug Administrations slogans, like "Buy your drugs from authorized persons, insist on Cash Memo, do not take sleeping pills without doctor's prescriptions, do not use drugs which are prescribed for others even though the symptoms are the same, " between their programmes regularly.

Shri Pany stated that there are less testing facilities available in his state and the laboratory is slowly coming up. He stated that Central Government should encourage the States either by funds or facilities. The Chairman explained that the Central Government had a Centrally sponsored scheme under which Central assistance was given to states for strengthening their testing facilities. However, the scheme has now been transferred to the State Sector.

Mr. Narasimhan felt that it is high time that uniform guidelines should be evolved in case of launching prosecutions.

Dr. Frias felt that now since Drugs Consultative Committee decisions are mandatory, a time limit should be set for their implementation.

Dr. Frias wanted to know whether in cases of adverse reactions of drugs, the Central Govt. should take action. The Chairman stated that the State Drugs Control

Authorities should normally take action. But in case of deaths the Centre could be informed.

Item No. 1 : Confirmation of the minutes of the last meeting of the D.C.C.

The minutes were confirmed with no change.

Item No. 2 : Action taken on the recommendation made by the D.C.C. at its last meeting.

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

(a) Consideration of the report of the sub-committee constituted by the twenty first meeting of the D.C.C. held in New Delhi in November 1979 to consider revision of Schedule P of the Drugs and Cosmetics Rules laying down life period of drugs.

The report of the sub-committee on the revision of Schedule P was discussed and the following decisions were taken :-

(1) Whole human blood to be included in the list.

(2) Life period of Paraldehyde Injection should be given as six months.

(3) References such as N.F.T., I.P. B.P. given against some of the drugs may be deleted.

(4) Note (a) and (b) regarding extension of life period of Vitamins and antibiotics appearing under 2(vi) in the main report and note (a) and (b) appearing in page 9 of the report may be deleted.

(5) Life period of formulations should not exceed the life period of bulk drugs.

(6) Storage conditions of drugs should also be included in Schedule 'P' and necessary changes made in Froms 21, 21-A and 21-B.

(7) A sub-committee consisting of Shri T. S. Venkataraman, Assistant Drugs Controller (India), and Shri V.C. Sane, Commissioner, Food & Drug

Administration, Maharashtra State will collect the data regarding storage conditions of drugs to be included in revised Schedule 'P'.

3(b) **Consieration of the report of the sub-committee constituted by the twenty-first meeting of the Drugs Consultative Committee for considering the item to be permitted for repacking under the Drugs & Cosmetics Rules in the light of the comments earlier received from State Drug Control Authorities.**

ANNEXURE – II

The Chairman explained that the sub-committee has prepared a revised list of items to be permitted for repacking. He said that the items permitted for repacking should essentially include those required by Hospitals, dispensaries and for household purpose. This list is for the guidance of the State Drugs Control Authorities but the same should be uniformly adhered to. Only in very particular situations one or two additional items may be permitted. After discussion the Committee approved the list of items as prepared by the sub-committee. It was also decided that the maximum packing size given in the list may be deleted and the minimum packing given may be taken as recommended size. Item 26 in the list may also be corrected to read as 'chlorinated lime I.P.'

(C) Consideration of the report of the sub-committee constituted by the twenty first meeting of the Drugs Consultative Committee to prepare a manual for guidance of Drugs Inspectors and Senior Supervisory Officers.

The Chairman appreciated the work of the members of the sub-committee in preparing for the first time a Manual for guidance of Drugs Inspectors and other supervisory officers. He requested all the State Drug Controller to go through the manual and forward their comments, corrections, if any, to the Chairman as early as possible so that the Manual could be finalized.

(d) Consideration of question of charging of extra fees for granting drug licences in the event of change in the constitution of the firm.

The Committee was of the view that by extending the period from 3 months to 6 months for applying for a licence in the event of change of constitution of the firm will not solve the problem. Shri Singh and Shri Gulati stated that if this offence could be made compoundable then this problem could be tackled. The Chairman stated that if the Committee could suggest specific amendment to the Drug and Cosmetic Rules then these could be got examined by the Ministry of Law. It was decided that a small group consists of the following members should prepare a report suggesting the changes in the Drugs & Cosmetics Rules regarding

compounding offences; so that Ministry of Law may be consulted in the matter.

1. Shri J. P. Singh
   Food & Drugs Admn., Madhya Pradesh.

2. Shri V. P. Gulati,
   Asstt. Drugs Controller, Delhi Admn.

3. Shri L. R. Gunay,
   Assistant Commissioner,
   Food & Drug Admn., Maharashtra State.

4. Shri K. K. Oza,
   Deputy Director, Food & Drugs Admn.,
   Gujarat State.

This report should be made available as early as possible for further necessary action.

3(e) Consideration of the report of the sub-committee constituted by the twenty-first meeting of the Drugs Consultative Committee to lay down the norms regarding minimum requirements of space and equipment in respect of institutions which carry out tests on drugs, cosmetics or raw materials used in their manufacture on behalf of licencees.

ANNEXURE – III

The Committee considered the report of the sub-committee which included inter-alia the requirement of space for Chemistry Laboratory, Microbiological Laboratory, Pharmacological Laboratory, lay-out of their plans and the list of sophisticated equipments for testing of drugs other than microbiological and pharmacological testing.

The committee accepted the report of the sub-committee which gives the essential guidelines for the licensing authorities for approval of laboratories for testing of drugs.

3(f) Consideration of prevailing formulation of Analgin Injection containing 0.5 gm per ml. in 2 ml. and 5 ml. packing on the basis of information received.

As comments from all the experts to whom the matter was referred have not been received, this item was not considered.

Item No. 4 : Consideration of the question whether the solution of methyl paraben (0.022%) and propyl paraben (0.01%) should be allowed to be used as a preservative in ophthalmic preparations.

It is observed from the market survey carried out on the eye drops containing esters of prahydroxybenzoic Acid as preservatives that most of the products (which contain either methyl paraben or propyl paraben or both) do not contain required concentration of total esters, 0.2% for the eye drops to be effective as a bacteriocide.

It was decided that the views of the manufacturers of ophthalmic preparations who are using methyl paraben and propyl paraben as preservatives may be ascertained.

Item No. 5 : Consideration of the question of entrusting the work of inspection and scrutinization of labels and literature of New Drugs by the Zonal Officers of the Central Drugs Standard Control Organisation.

The Committee agreed that Zonal Officers of the Central Drugs Standard Control Organisation could scrutinize the labels literature of manufactures in their zones to see whether the warning statements etc. are being given. The deficiencies will be brought to the notice of the State Drugs Control Authorities for taking necessary action in the matter.

Item No. 6 : Training programme of Drugs Inspectors sponsored by the Central Drugs Standard Control Organisation suggestions from the Director, Food & Drugs Admn., Gujarat State to make the programme more useful.

Director, Food & Drugs Administration, Gujarat, made some valuable suggestion for making the training programme more comprehensive and useful.

It was agreed to appoint a sub-committee with the following composition for the purpose of laying down the details of the training programme for Drugs Inspectors as well as Supervisory Officers who are enforcing the provisions of the Drugs & Cosmetics Act and the Rules thereunder :-

1)	Director, Food & Drugs Admn., Gujarat State	Chairman
2)	Drugs Controller, Madhya Pradesh	Member
3)	Drugs Controller, Andhra Pradesh	Member
4)	Drugs Controller, Karnataka	Member

5)	Commissioner, Food & Drugs Admn., Maharashtra State.	Member
6)	Director, Drug Control, West Bengal	Member
7)	Dy. Drugs Controller(India) Drugs Inspectorate Training Scheme C.D.S.C.O., Bombay.	Member (Convener)

Item No. 7 : Training facilities in analytical procedure to fresh science graduates.

The Chairman explained that the Drugs Controller, Rajasthan had informed that the manufacturers of drugs especially in the small scale sector have been experiencing difficulty in employing suitable persons with adequate experience in testing and analysis of drugs, in their quality control laboratories and suggested that some training programmes may be arranged for fresh B.Sc. graduates. The Indian Drugs Manufacturers Association has shown willingness to conduct short term training courses in collaboration with some colleges of pharmacy in different parts of the country.

It was agreed after a considerable discussion to constitute a sub-committee to lay down details of the training courses for B.Sc. as well as B. Pharma graduates for testing and analysis of drugs :

1)	Drugs Controller, Karnataka	Chairman
2)	Director, Central Drugs Laboratory	Member
3)	Drugs Controller, Madhya Pradesh	Member
4)	Drugs Controller, Tamil Nadu	Member
5)	The Director, Food & Drugs Admn., Gujarat State.	Member
6)	Dy. Drugs Controller (India) C.D.S.C.Orgn., South Zone, Madras	Member (Convener)

The details of the training course, when finalized by the Committee, can be passed on to Indian Drug Manufacturers Association for their action.

Item No. 8 : Consideration of the question whether permission shall or shall nto be given for the manufacture of new drugs under a loan licence.

It was decided that whenever a manufacture approach for permission to manufacture a new drug, he should produce a photo copy of the manufacturing licence issued by the State Drugs Control Authorities. If he has no manufacturing licence in Form 25 or 28, no new drug permission will be given. The Chairman stated that this could be done only in case of new drugs approved in future.

(Please refer to minutes of item 27)

Item No. 9 : Marketing of antibiotic liquid oral preparations in 60 ml. packs and supply of measuring spoon with all liquid oral preparations.

The Committee agreed that a plastic spoon should be supplied with the pack of antibiotic liquid oral preparations. Dr. O. P. Sharma, Drugs Controller, Delhi Administration was requested to give a list of antibiotic pediatric preparations where a spoon is required to be given.

Item No. 10 : Marketing of products containing protein Hydrolysate, fats carbohydrates with of without vitamins.

The Committee agreed that whenever a preparation containing protein, carbohydrates, vitamins etc. is marketed as a food supplement and no therapeutic claims are made in the label, then such a preparation should be considered as a 'food product.' However, if therapeutic claims are made on the label, the preparation should be considered as a drug. The decision should be uniformly implemented by the State Drugs Control Authorities.

Item No. 11 :Advertisement of cosmetics – Need for protecting consumers from tall claims.

The Committee decided that whenever any tall claims are made on the label of the cosmetics, the manufacturer may be asked to delete such claims from the label.

Item No. 12 : Sugar coating of formulations containing oxyphenbutaz –one.

The question whether products in combination oxyphenbutazone, when single formulation of oxyphenbutazone is required to be coated, should be coated or not was discussed. As the members expressed views in favour and against of coating of such formulations, no decision was taken. However, it was decided that when a single ingredient tablet of a drug is required to be coated the State Drugs Control Authorities should ask the manufacturer to submit adequate data for not coating such a drug in combination before licensing its manufacture.

Item No. 13 : Suggestions from "Delhi Drugs Manufacturing Association" regarding administration of the provisions of the Drugs & Cosmetics Act and the Rules thereunder.

The following points made by the Delhi Drugs Manufacturing Association were agreed to.

(1) While approving formulations of patent or proprietary medicines, the therapeutic rationale should be considered.

(2) Whenever a sample is declared as not of standard quality on technical grounds (e.g. colouring / coating of tablets) the matter may be sorted out amongst the two State Drugs Controllers i.e. where the sample has been lifted and where it is manufactured.

The question of limiting the licensing for manufacture of combination was discussed. The Chairman was of the view that it was necessary to restrict the licence of manufacture of combinations to the minimum.

At his request the members agreed to forward to the Drugs Controller (India) the list of new combinations licensed by them every quarter.

Item No. 14 : (i) Filling of tablets in capsules.

As the formulation Hemisules marketed by M/s. Talento Pharmaceuticals, Bombay has been licensed by the Commissioner, Food & Drug Administration, Maharashtra State, he Chairman requested him to give details and reasons for allowing such formulation. The Committee was of the view that tablets should not be filled in capsules.

(ii) Extension of time limit for freezing of drugs.

The Committee did not agree to extend time limit from 20 days to 60 days for freezing of drugs.

Item No. 15 : Household remedies sold by traders in villages – exemption from taking out a sale licence under the Drugs & Cosmetics Rules.

The Committee unanimously agreed that no further concession need be given to small traders selling household remedies, as the fees charged at present for sale licence is very nominal.

Item No. 16 : Cancellation of licence – preferring of appeal petition – time limit.

The Committee was of the view that the present provision for preferring an appeal against an order of the licensing authority, within 3 months from the date of order is adequate.

Item No. 17 : Consideration of the question whether manufacture of Mehandi Powder should be controlled under the Drugs & Cosmetics Act and Rules.

The Committee was of the view that manufacture of Mehandi Powder need not normally be licensed. However, if a manufacturer wants his product to be covered by a manufacturing licence for meeting the requirements of the exporting country then the product could be licensed.

Item No. 18 : Labelling of pediatric drug products with symbolic pictures.

The Committee was of the view that it would not be practicable to have pictures of eye, ear, mouth etc. on the labels of the pediatric drug products.

Item No. 19 : Marketing / Manufacturing of a preparation by a loan licensee when the parent firm has not been permitted to either market or manufacture the same item.

The Committee decided that the parent manufacturer must possess a licence for the category of drugs to be manufactured by the loan licensee though he may not have a manufacturing licence for all the items manufactured on behalf of loan lincecees.

Item No. 20 : Sale of drugs by wholesaler in split quantities.

The representative of Andhra Pradesh stated that wholesalers sell drugs in split packing whenever there is short supply and desired to know whether this should be allowed. The practice in other States was also the same.

The Chairman explained that the wholesaler should sell the drugs only in original packs supplied by the manufacturers and should on no account sell in split packings. He stated that if required, a rule will be introduced in the Drugs & Cosmetics Rules to prohibit wholesalers to sell drugs in split packings.

Item No. 21 : Amendment of Rule 138 and 139 of the Drugs and Cosmetics Rules regarding manufacture of cosmetics for sale.

Dr. Kaul stated that the Rules for manufacture of cosmetics for sale have now been enforced for over seventeen years and he was of the view that different scales of fees and different qualifications for the technical staff

based on the number of workers employed by a cosmetics manufacturing firm may be dispensed with.

Though representative of Tamil Nadu and West Bengal expressed the fear that there will be hardship to the new units, the consensus of opinion was that the existing manufacturers should be allowed to continue and the scales of fee and qualifications of the personnel may be rationalized. The Chairman explained that the manufacturers have some responsibility towards the consumer and more control is required to be exercised.

It was decided to amend the concerned Drugs & Cosmetics Rules, accordingly.

Shri Singh raised a question of licensing fee per additional item, as the applications are received with a list containing a large number of items.

The Committee agreed that there should be licence fee for the limited number of items and Rs.5/- per additional item at the time of licensing and renewal of licences.

Item No. 22 : Enforcement of the provisions laid down in Part XII B of Schedule 'F' for the Blood Banks.

The representative of Delhi Administration raised some questions whether bleeding of donors by Blood Banks outside their licensed premises should be permitted, if so the precautions to be taken to ensure hygienic conditions and freedom from contamination, whether Blood Banks who manufacture their own A.C.D. solution should have premises, equipment and technical staff similar to a manufacturer producing large volume parenterals; the details of the medical examination of the donors, etc.

After careful discussion, it was decided to constitute a sub-committee with the following composition to look into all aspects of the matter and suggest revision of Schedule F for the Blood Banks.

1.	Drugs Controller Delhi Administration	Chairman
2.	The Commissioner, Food & Drug Administration, Maharashtra.	Member
3.	Drugs Controller, Karnataka	Member
4.	Director, Drug Control, West Bengal, Calcutta.	Member

5.	Dr. I. D. Sharma, A.I.I.M.S., Blood Bank Deptt., New Delhi.	Member
6.	Deputy Drugs Controller, Central Drugs Standard Control Organisation, North Zone, Ghaziabad.	Convener

Item No. 23 : Regarding hair oils labeled to contain Amla, Brahmi, Caster Oil, etc.

Dr. Kaul stated that a number of hair oils are marketed as Amla Oil, Brahmi Oil, etc. although they do not contain actual Brahmi or Amla but contain mineral oils and essence.

The Chairman explained that hair oils such as Amla Oil, Brahmi Oil etc. should be manufactured in accordance with the Ayurvedic system but should be licensed as cosmetics. If these oils contain essence of Amla, Brahmi, etc., they should be labeled accordingly.

Item No. 24 : Coating of single ingredient pharmacopoeial drugs manufactured under brand names.

The Committee was of the view that single ingredient tablets marketed under generic or brand name should not be permitted to be coated / coloured if the pharmacopoeia does not specifically permit coating / colouring for such tablets.

The Chairman requested the State Drugs Control authorities to ensure that the manufacturers in their States should not market tablets included in the Indian Pharmacopoeia, beyond 1981. Such preparations would be declared as Not of Standard Quality after 1981. Till that time the Analysts may declare the samples as of standard quality but add a note at the end of the report stating that coating / colouring has not been permitted in the Pharmacopoeia.

Item No.25-26: (i) Inspection of premises of selling shops and manufacturing firm ;

(ii) Licence to sell drug in the same premises.

As the Drugs Controller, Bihar, was not present there items suggested by her were not considered.

Item No. 27 : Loan licensing policy.

The representative of Rajasthan and some other State Drugs Controllers complained that the decisions taken in the last meeting of the Drugs Consultative Committee about loan licensing policy are not being implemented in some States. The Chairman explained that when the rules are published and made official, there will be no question of deviation. He stated that whenever a decision has been taken in the Drugs Consultative Committee, the same should be uniformly implemented. If any member has any difficulty, he should refer the matter to the Chairman for clarification.

The Drugs Controller, Madhya Pradesh raised a question whether only a total of ten items should be allowed on loan licence or ten items per category. After considerable discussion the Committee agreed that (i) (Not more than six units should be given on loan licences with a single manufacturer and (ii) the items allowed to be manufactured per unit should not normally exceed 20 subject to a maximum of 120 items with a manufacturer.)

The representative of Maharashtra stated that in Maharashtra there are many loan licences doing job 25 to 30 parties and this could be brought down only gradually.

The Chairman stated that no new loan licence for injection should be issued and no strip packing should be allowed on loan licences.

The Chairman stated in reply to a query from the representative of Rajasthan that if there is no objection from any of the two States, the loan licensing should continue even on inter-state basis. He also stated that no exemption should be given in respect of ophthalmic sterile preparations and practice followed in respect of gamma radiation and sterilization should continue.

Item No. 28 : Survey sampling of vaccines and sera under N.S.Q.E.D. Programme.

The Chairman stated as already requested the State Drugs Control authorities should send samples of sera and vaccines to Director, Central Research Institute, Kasauli as required by the Vaccine Control Board. He further stated that samples of polio vaccine may be sent occasionally as per suggested procedure. The samples of sera and vaccine could also be tested in other institutions having facilities for testing.

Item No. 29 : Action against RMPs found contravening the provisions of Schedule K.

The Chairman stated that whenever the RMPs are found to purchase drugs from unlicensed dealers or contravene the provisions of Schedule K of the Drugs and Cosmetics Rules, they could be prosecuted.

Item No. 30 : Consideration of the question of making provisions under the Drugs & Cosmetics Rules 1945 regarding discretionary powers to the Licensing Authorities in respect of insisting for having own testing laboratories for manufacturing units.

The Chairman explained that as per rules a manufacturer should have a testing laboratory of his own. So far as new units are concerned they should have their own laboratories for testing. However, in case of existing units the State Drug Control Authorities may use their discretion in respect of testing of certain sophisticated items. The manufacturers of medicinal gases should have their own testing facilities.

Item No. 31 : Consideration of the question as to whether Kum Kum of red and yellow colours should be covered under the definition of Cosmetics as given in the Drugs and Cosmetics Act, 1940.

Since there is a decision by the Madras High Court that red and yellow Kum Kum are being used for religious purposes and that they should not be treated as cosmetics, the Chairman stated that State Drug Controllers need not licence these products as cosmetics. However, if a manufacturer is manufacturing Kum Kum in liquid form of different colours which are generally not for religious purposes, the same could be licensed as cosmetics.

Item No. 32 : Consideration of the question of giving discretionary powers to the licensing authority to approve a competent technical person for analyzing surgical dressings.

The Chairman stated that so far as new units are concerned the qualifications of technical competent person for manufacture as well as technical person for supervising analysis of surgical dressings should be as required in the amended Drugs & Cosmetics Rules. However, in case of existing units the licensing authority may use his discretion for approving the technical person for supervising the testing of surgical dressings.

Item No. 33 : Difficulties / clarification relating to Ayurvedic (including Siddha) and Unani medicines and Homoeopathic medicines.

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

(a) Manufacture of Ayurvedic Injections

It is understood that Ayurvedic Injections are manufactured in Andhra Pradesh and Uttar Pradesh.

The Deputy Adviser (Unani) explained that a team of Government officials has inspected the manufacturing units of Ayurvedic injections and these units are found to possess to a larger extent necessary requirements for giving the licence. The second question is to decide whether these injections are useful or not. A team is likely to discuss this with Doctors who are using these injections. The final recommendations of the team may be awaited.

In reply to a query the Chairman stated that an Injection containing Ayurvedic with Allopathic drugs will be considered as a new drug.

(b) Consideration of the question of including a provision in the Drugs and Cosmetics Act 1940 so as to take action for the manufacture and marketing misbranded ayurvedic drug.

The Chairman stated that provision is being made in the Drugs & Cosmetics Rules regarding manufacture and marketing of misbranded Ayurvedic drugs.

(c) Selling of ayurvedic preparations whose proprietary names resemble allopathic drugs.

Hakim Razzack explained that the Central Council of Health has passed a resolution two years back stating that manufacturing and marketing of Ayurvedic drugs resembling allopathic drugs, should not be permitted. He agreed to supply a copy of the resolution.

(d) Consideration as to whether some Ayurvedic preparations falling on the border line of Drugs & Cosmetics could be classified as cosmetics only.

The Deputy Adviser (Unani) stated that A.U.D.T. A.B. had discussed about patent or proprietary ayurvedic drugs and the guidelines will be circulated when finalized. He requested the members to forward to him, if they have nay suggestions in the matter.

He clarified that if cosmetics are marketed as ayurvedic drugs, then they should be manufactured as stated in the Ayurvedic text books. He further clarified that sharbats manufactured according to provisions of Ayurvedic books and medicinal claims are made on the labels of such sharbats then hey could be considered as ayurvedic otherwise not. He also stated that

tablets / capsules manufactured by Ayurvedic manufacturers may be considered as Ayurvedic drugs, if they contain only ayurvedic ingredients. The Chairman stated that all soaps including Ayurvedic soap are beyond the pruview of the Drugs & Cosmetics Act.

(d) Fixing of percentage of alcohol in Mrit Sanjeevani Sura and other pharmacopoeial Alcoholic Ayurvedic and Unani drugs.

Dr. Gupta, Director of Ayurvedic and Unani Services, U.P. stated that there is no mention of percentage of self generated alcohol in Mrit Sanjeevani Sura and the Drugs & Cosmetics Act & Rules provide no statutory support to the licensing authority to fix and regulate percentage of alcohol in Mrit Sanjeevani Sura.

The Chairman stated that data on Mrit Sanjeevani Sura may be supplied so that this could be considered by A.U.D.T.A.B.

(f) Publication of Ayurvedic Pharmacopoeia.

Hakim Razzack stated that Ayurvedic Pharmacopoeia Committee is already on the job of Ayurvedic Pharmacopoeia and work would be expedited.

(g) Labelling provisions for Ayurvedic, Siddha and Unani drugs.

The Committee agreed to maintain status quo in regard to labeling of Ayurvedic, Siddha and Unani drug samples distributed free of charge.

(h) Cosmetics containing Ayurvedic ingredients (such as termaric powder, Neem oil, sandalwood powder and oil etc.) to be considered as cosmetics.

This has been discussed under (d) above.

(i) Standards of Ayurvedic drugs.

The Chairman stated that it is not possible to permit manufacture of Ayurvedic drugs included only in Ayurvedic formulary of India, Part I published by the Government of India, Ministry of Health & Family Welfare and Pharmacopoeial Standards for Ayurvedic formulations published by Central Council for Research in Indian Medicines and Homoeopathy. He further stated that the present practice should continue.

(j) The procedure to be followed for licensing of the Patent or Proprietary medicines.

This was already discussed under (d) above.

(k) The provisions of Rule 106 for the Ayurvedic and Unani drugs.

The Committee agreed that no action be taken to include in Rule 161 of the Drugs and Cosmetics Rules provisions of Rule 106 – Diseases which a drug may not purport to prevent or cure.

(l) Consultation with the expert in Ayurvedic Systems of Medicines for the approval of the formula.

The Committee did not agree with the suggestion that the licensing authority should consult experts in respect of approval of formula of only Patent or Proprietary preparations. Even in respect of preparations other than Patent or Proprietary the licensing authority could consult experts if considered necessary.

(m) Action for sub-standard Ayurvedic drugs.

The Chairman clarified that no legal action could be taken against the manufacturer whose samples of Ayurvedic drug has been declared as not of standard quality. However, administrative action could be taken against the manufacturer.

(n) Appointment of Kaviraj as a Competent Technical staff for manufacture of Ayurvedic drugs.

The Chairman clarified that a competent technical person is required to supervise manufacture of Ayurvedic tablets and capsules.

(o) Manufacturing of Ayurvedic and Homoeopathic ingredients as Hair Oil under Cosmetics Licence.

This has been discussed under item No. 23.

Problems relating to Homoeopathic medicines.

At the invitation of the Chairman, Dr. Diwan Harish Chand, Hony. Adviser (Homoeopathy), Ministry of Health & F.W., attended the meeting for giving the necessary clarifications on matters relating to homoeopathic medicines.

The Chairman stated that the sub-committee appointed by the twenty –first meeting of the Drugs Consultative Committee to suggest revision of Schedule M1 for laying down the details of the minimum equipment,

space required for the manufacture of Homoeopathic drugs has submitted the report which has been circulated for information of the members.

The representative of Delhi Administration liked to know about licensing of combinations of homoeopathic medicines.

Dr. Harish Chand stated that the Government of India in order to make standard formulae of homoeopathic medicines had addressed to all State Governments to give full information regarding the approved patent and proprietary combinations of Homoeopathic medicines. Though information has been received from some of the State Governments, the information is still awaited from Maharashtra, West Bengal, U.P., Assam, Kerala, Manipur, Jammu & Kashmir and Tamil Nadu. He further stated that after getting the information a list of approved Patent or Proprietary Homoeopathic medicine would be compiled and circulated.

(p) Sale of Homoeopathic medicines.

The Drugs Controller, Karnataka desired to know who should be approved as a competent person to supervise sale of Homoeopathic medicines.

It was clarified that a literate person having some experience in Homoeopathy may be considered as 'competent person' for sale of homoeopathic medicines.

The Adviser in Homoeopathy stated that the chemists can sell Homoeopathic medicines provided the medicines are sold in the original container.

The Chairman requested the members to forward their views as to whether the time is ripe for fixing some qualifications for persons supervising sale of Homoeopathic medicines.

Item No. 34 : Consideration of the question of providing for administrative action against firms who change constitution after commission of irregularities and thereby escape punishment.

The Chairman stated that this is a legal issue and no administrative action is possible when firms change their constitution after commission of irregularities and thereby escape punishment.

Item No. 35 : Consideration of question of providing for prohibition or regularization of free supply of drugs made in sales promotion scheme.

The Chairman explained that the free supply of drugs made in sales promotion scheme is not a problem under the Drugs & Cosmetics Rules and no action is necessary.

Item No. 36 : Consideration as to whether the different floors occupied by a manufacturing company in an Industrial Estate Building Complex could be regarded as a separate set of premises for grant of separate manufacturing licences.

The Chairman stated that generally one licence may be issued when two premises of the same company are situated in the same building. If the building is very large and the premises are separated by appreciable distance the State Drugs Control authorities could use their discretion.

In reply to a query made by the representative of Maharashtra State, the Chairman stated that no separate licence need be given to the testing laboratory when the manufacturer's manufacturing premises are at one place and his testing laboratory is in another area.

Item No. 37 : Consideration as to whether partners of approved commercial testing laboratory, who are having a manufacturing sister concern can avail of the facility of this approved testing laboratory without having laboratory of a manufacturing firm.

After considerable discussion the committee decided as follows:

(1) A manufacturer having a sister concern – an approved commercial laboratory, preferably situated at the same campus, can avail of the facilities of this approved laboratory for testing of their drugs.

(2) 3 or 4 group firms can have a single testing laboratory of their own.

(3) Two different manufacturers cannot utilize the testing facility available with only one manufacturer.

(4) A manufacturer having two manufacturing firms in the same city can have one testing laboratory.

Item No. 38 : Consideration as to whether approval of technical staff in drug manufacturing concern a post-graduate or a Doctorate degree could be taken into consideration for reducing period of experience laid down in the rules 71(1) and 76(1) of the Drugs & Cosmetics Rules.

The Chairman stated that the minimum qualifications as stated in rules 71(1) and 76(1) of the Drugs & Cosmetics Rules should not be changed.

However, in case of persons possessing post-graduate or doctorate degrees the licensing authority can exercise his discretion.

Item No. 39 : Consideration as to whether the term 'deal with' is to be constructed as to 'deal in' in the recently amended Rule 64(2) of the Drugs & Cosmetics Rules.

The Chairman clarified that a Medical Representative is not considered as dealing in medicines and stated that the licensing authority should exercise his discretion about the person to be approved.

Item No. 40 : The Drugs & Cosmetics Act enables the Courts to publish the name of the offenders etc. in case of his conviction vide Section 35 of the Drugs & Cosmetics Act 1940.

The Chairman stated that the relevant section is being amended to include hat if a person has been convicted by the court, the Drugs Inspector can ask for permission of the court to publish the report at his expense.

Item No. 41 : Consideration of making it mandatory for maintenance of Inspection Book in respect of licences in form 20BB, 21BB, 28A, 20C, 20D, 25D and 25E.

The Committee agreed that the provision should be made to make it mandatory for maintenance of Inspection Book by the licencees holding licences in form 20BB, 21BB, 28A, 20C, 20D, 25D and 25E.

Item No. 42 : Consideration of inclusion of 'Paradeep Port' as one of the places for import of drugs into India by sea by suitably amending Rule 43-A of the Drugs & Cosmetics Rules.

The Chairman stated that in view of the experience of Visakapatnam which is an authorized Port of entry but which has registered no import of drugs and medicines for 3-4 years, it is not practicable to include 'Paradeep Port' as port of entry of drugs into the country.

Item No. 43 : Action to be taken in regard to the samples of drugs found not of standard quality on their test / analysis by the Government Analysts.

The Chairman stated that there was no uniformity of action in the States so far as sub-standard drugs are concerned. Members of Parliament have also expressed concern that adequate action against manufacturers whose drugs are reported to be not of standard quality is being taken. He felt that it was necessary to lay down suitable guidelines so that action on an uniform basis is taken in case of sub-standard drugs throughout the country.

After some discussion, the Committee decided to constitute a sub-committee with following composition to prepare guidelines for the action to be taken in the case of drugs declared to be as not of standard quality by the Government Analysts. This sub-committee will also review the guidelines issued in regard to prosecution of the firms and prepare revised guidelines. The sub-committee should submit the report by October 1981 :-

1.	Director, Drugs Control, West Bengal	Chairman
2.	Jt. Drugs Controller, Tamil Nadu	Member
3.	Commissioner, Food & Drug Admn., Maharashtra State	Member
4.	Director, Food & Drug Admn. Gujarat	Member
5.	Drugs Controller, Goa	Member
6.	Drugs Controller, Orissa	Member
7.	Drugs Controller, Karnataka	Member
8.	Deputy Drugs Controller, Haryana	Member
9.	Drugs Controller, Delhi Admn.	Member
10.	Deputy Drugs Controller, South Zone Madras	Member (Convenor)

Item No. 44 : Number of containers required for testing.

The Chairman explained that provisions of Indian Pharmacopoeia will prevail over those of Drugs & Cosmetics Rules and action will be taken to amend the concerned rules.

Item No. 45 : Disposal of drugs seized under Section 22(1)(c) of the Drugs & Cosmetics Act, 1940.

The Chairman stated that a sample of the confiscated goods should be tested and if found to be not of standard quality then permission of the Court should be taken for destruction of the goods.

Item No. 46 : Manufacture of drugs by hospitals.

The Committee decided that in view of the Patna High Court judgement the hospitals manufacturing intravenous fluids and human blood I.P. etc. should be licensed.

The Chairman clarified the points raised by the Drugs Controller, Karnataka as follows :

(1) The Medical Superintendent should apply for a license for hospital manufacturing intravenous fluids.

(2) Manufacturing in hospital should be done under the supervision of a pharma graduate and they should have facilities for testing.

(3) Blood Banks in big cities should at least be licensed if it is not feasible at present to licence blood banks in small towns.

Item No. 47 : Multi-dose containers for injectables.

The Committee decided that the multiple dose containers for injectables should be such that they should not contain more than 10 doses.

Item No. 48 : Approval of Technical Staff under Rule 71(1)(b) and 76(1)(b).

The Chairman stated that for the purpose of Rule 71(1)(b) and 76(1)(b) a graduate in science with chemistry as one of the subjects may be considered.

Item No. 49 : Black listing of manufacturers found indulging in malpractices.

The Committee felt that while manufactures engaged in the manufacture of spurious drugs etc. should be proceeded against the circulation of their names to the other State Drug Control Authorities may not serve much purpose as the State Drug Control Authorities would not be able to take action. Further, such a circular may result in legal problem.

Item No. 50 : Establishment of their own laboratories by manufacturing units.

This was discussed under Item No. 37.

Item No. 51 : List of laboratories.

The Chairman stated that a list of approved laboratories is being compiled and will be circulated.

Item No. 52 : Licensing of hospital pharmacies.

This was discussed under item No. 46.

Item No. 53 : Whether new drugs and drugs under Schedule W can be permitted for marketing under Brand name in combination.

The Chairman stated that with the publication of the new amendment to the Drug & Cosmetics Rules requiring manufacturers to market single ingredient preparation of certain drugs under generic names only the manufacturers have started making applications for the manufacture of combination with a view to by passing the provisions of the Drugs and Cosmetics Rules.

He desired that the State Drug Control Authorities should not licence combinations of new drugs and drugs under Schedule W with other drugs for marketing under a brand name and such combinations may be referred to this Directorate for approval.

Item No. 54 : Control over manufacture of sanitary towels.

Dr. Das stated that sanitary towels are manufactured under unhygienic conditions and they should be brought under the purview of Drugs & Cosmetics Act.

The Committee felt that as sanitary towels would not come within the purview of the definition of the term drug it would not be possible to regulate its manufacture under the Drugs & Cosmetics Act.

Item No. 55 : Composition of Cosmetics for checking colour and hazardous substances.

The Chairman explained that the manufacturers of cosmetics have agreed to give the list of ingredients added in the cosmetics to the licensing authorities and the licensing authorities should check this list of ingredients before the manufacturer is allowed to manufacture the cosmetics.

Item No. 56 : Stocking of samples by R.M.Ps.

The Chairman stated that if the R.M.Ps. contravene the provisions of the Drugs & Cosmetics Rules, they may be proceeded against.

Item No. 57 : Any other item with the permission of the chair.

(a) Inspection of the testing laboratories of the States.

The representative of Gujarat stated that there are no statutory requirements for insisting specific areas for different manufacturing sections as given in Schedule M.

The Chairman stated that the Good Manufacturing Practices have not been included in the Drugs & Cosmetics Rules because the industry had requested for some more time. The time is now proper to include G.M.Ps. in the Drugs & Cosmetics Rules.

The Chairman stated that a small group consisting of Deputy Drugs Controller (India) HQrs, Deputy Drugs Controller (India) North Zone and Deputy Drugs Controller Delhi Administration will redraft G.M.Ps. taking into consideration G.M.Ps. which had been prepared earlier and G.M.Ps. published by W.H.O.

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

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