MINUTES OF THE 26th MEETING OF THE DRUGS CONSULTATIVE COMMITTEE HELD ON 14th & 15th SEPTEMBER 1989

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MINUTES OF THE 26TH MEETING OF THE DRUGS CONSULTATIVE COMMITTEE HELD ON THE 14TH & 15TH SEPTEMBER 1989

Dr. Prem K. Gupta, Drugs Controller (India) welcomed the members and apologized for not being able to convene the Drugs Consultative Committee meeting earlier due to unavoidable reasons. He welcomed Shri R. Srinivasan, Secretary (Health) and Mrs. Vineeta Rai, Joint Secretary (Health). The members then introduced themselves and Dr. Gupta requested Secretary (Health) to address the members.

The Secretary (Health) brought to the notice of the members that several Parliament Questions are being asked on drugs by Members of Parliament in both the Houses and the State Drugs Controllers should remain vigilant about complaints on quality of drugs specially those appearing in press. Such complaints should be properly investigated and the findings should be communicated to Central Government on priority basis. He informed the members about the concern caused in the country due to detection of HIV contamination in blood product at All India Institute of Medical Sciences and the action that had to be taken by Central Government to ensure that all the blood products manufactured in the country are free from HIV antibodies and other contaminants. He reminded the members about the need to have a full time qualified Drugs Controller in each State. He also commented on the inadequate organizational set up of the Drugs Control Administration of the States and Centre with shortage of drug inspectorate staff as well as lack of testing facilities in the States. He pointed out how the finding of Lentin Commission had shocked everybody. Mr. Srinivasan suggested that D.C.C. should meet twice a year and one meeting should be held a week or 10 days before the C.C.H. meeting. He also desired that Secretary, Department of Chemicals and Petrochemicals

should be invited to participate in the DCC meetings so that members can clarify their doubts regarding enforcement of Drugs (Price Control) order and also about the availability of drugs. He further suggested that drug industry should also be intvited to share their views with the State Drugs Controllers.

While suggesting restructuring of State Drugs Control Administrations, he recommended that an independent Drugs Controller in each State should be assisted at Head Quarters by an officer of the rank of Additional or Joint Drugs Controller, Officers of the level of Deputy Drugs Controllers at the field level should guide and supervise the work of Drugs Inspectors and intermediary officers. He suggested that a small group consisting of Mr. B.B.Sharma and Drugs Controllers of other States should lay down the duties and responsibilities of different levels of officers in a State set up. A note prepared by the Group is at **Annexure I**. Secretary (Health) advised the members to see that effective action is taken to monitor prices and availability of drugs. While permitting drug formulations for the first time or at the time of renewal of licences, rationality of various formulations permitted by them should be examined.

The Secretary (Health) emphasized the need to have testing laboratories and augmentation of Drugs Inspectorate staff in each State. He also desired that arrangements for training of Drugs Inspectors should be made by Central Government at 3-4 training centres. Mr. Srivinvasan suggested that these centres should consider issuing bulletins containing information on technical and legal matters including various court decisions on drugs. Secretary pointed out that in States like U.P., Bihar, Haryana, Madhya Pradesh and Punjab etc. the enforcement of Drugs and Cosmetics Act is much weak as compared to some other States. He desired that this situation must be remedied. He was of the opinion that the State Drugs Controllers should make efforts to identify places where sale of drugs is disproportionately more in particular areas or at a particular time of that year when there are chances of selling sub-standard and spurious drugs. It was suggested that Drugs Controller (India) should set up a task force to tackle the problem of inter-state movement of sub-standard and spurious drugs. Suitable Intelligence-cum-Legal cells should be established at Centre and in States to unearth rackets involved in the movement of sub-standard and spurious drugs. Secretary (Health) was also concerned about the need for effective recall of drugs which are found to be toxic and haradous to public health. He desired that a methodology should be devised to see that information in case of such drugs is passed on and the use of such drugs is effectively stopped within 72 hours even upto the level of hospitals an consumers at large. The Drugs Controllers should insist for documentary evidence about communication of information on sub-standard drugs from manufacturer to distributor, wholesaler, retailer, etc. so that effective recall of drugs is possible in its true sense.

In conclusion he referred to the arrangements which are being made for ensuring the availability of safe blood and blood products in the country. He stressed that blood banks should be licensed by the State Drugs Controllers and while licensing Government blood banks if necessary, discretion may be used in respect of space, equipment, etc. which does not affect the quality of blood.

At this stage Secretary and Jt. Secretary thanked the members and had to leave for another meeting.

The Chairman introduced to the members Dr. Verma, Director (EMR) who is involved in the scheme of modernization of blood banks in the country. He stated that it is Governments' intention to ensure that all blood available in the country should be safe and free from HIV antibodies and Hepatitis-B surface antigen. Dr. Verma circulated a paper prepared by him viz. 'Scheme for Modernisation of Blood Banks'. He said that this paper gives details on what action is required to be taken where blood banks are operating or where blood products are manufactured. He informed the members of the arrangements made by Central Government for testing of blood for HIV antibodies at various surveillance centres established by ICMR. Dr. Verma informed that in due course facilities for HIV testing will be extended to cities with 5 lakh population.

Drugs Controller (India) informed that about 60% of the blood is collected in the metropolitan cities of Bombay, Madras, Calcutta and Delhi and therefore effective check in these four cities will reduce the problem to large extent. Drugs Controller (India) requested the State Drugs Controllers to notify surveillance centres identified by Central Government as approved laboratories for testing of blood for HIV antibodies. While considering para 12.2 of the paper circulated by Dr. Verma, the Committee agreed to most of the suggestions and made some additional points. The recommendations made by the Committee are given in **Annexure II**.

After lunch the Chairman informed the members about the sad demise of the following past members who have contributed a lot in D.C.C. meetings :

1. Shri S. S. Kattishettar, Drugs Controller, Karnataka.
2. Shri M. R. Kerudi, Joint Drug Controller, Karnataka.
3. Dr. V. Perumal, Drugs Controller, Tamil Nadu.
4. Dr. Janardan Das, Director Drugs Control, West Bengal.

He requested the members to observe two minutes silence in the memory of the departed souls.

The Chairman observed that many things have happened since the last meeting and we must take stock of the existing enforcement in each State. He stated that Good Manufacturing Practices (GMPs) have been incorporated in the Drugs and Cosmetics Rules and it is hoped that the enforcement has been initiated in each State. He requested the members to comment on the level of acceptance of GMPs by manufacturers and the extent of implementation in their State. He also mentioned about the amendment concerning New Drugs, viz. Schedule 'Y' of Drugs and Cosmetics Rules, according to which a New Drug has been defined and a combination of existing drugs, a new delivery system or a new dosage form will be created as 'New Drug' and that State Drugs Controllers should not permit any of these till the manufacturer gets the necessary permission from Drugs Controller (India).

While elaborating on action taken on blood and blood products, he told that all the products manufactured indigenously had to be withdrawn and destroyed and their production stopped. He said that as per the new guidelines issued, every blood unit collected by blood bank or collected for further processing for manufacture of a blood product need invariably be tested for presence of HIV antibodies. That in case of units manufacturing blood products besiders HIV testing at various stages, the procedure adopted for processing should include step which ensures inactivation of all viruses.

Dr. Gupta also stated that in case of imported blood products, a certificate from the manufacturer stating that the product has been manufactured from blood which is free from HIV antibodies is required to be furnished and the product is also tested before release.

He informed the members that a High Powered group under the Chairmanship of Health Minister of Maharashtra has been constituted as per the recommendations of the Central Council of Health. The group has already held two meetings and some of the major points that are under consideration of the group are –

1. Strengthening of Central Drugs Standard Control Organisation.

2. Provision for 100% Central assistance to the States to create / upgrade testing laboratories.

3. Providing assistance by Central Govt. for strengthening of Drugs Inspectorate staff.

4. Strengthening of procedure for quick recall of drugs in emergency situations.

Dr. Gupta expressed that information systems at the States and Centre are grossly inadequate. It is necessary that States should develop computerized information system wherein such important information like number of licences granted; number of samples collected' samples found sub-standard and spurious; prosecutions launched and convictions and punishment awarded etc. should be stored and should be readily retrievable. He further mentioned about tightening of enforcement at retail leval as it is alleged that potent drugs are readily available without prescription. Control of Ayurvedic an Homoeopathic drugs will also need tightening. He brought to the notice of the members that brand names of some Ayurvedic and Homoeopathic drugs which are very similar to Allopathic drugs, sometimes even such allopathic drugs which have been banned thereby creating confusion in the mind of the public. The other area of concern is the action taken on the sub-standard drugs which is widely criticized. He said that suspension for two or three days is an action more on paper and not a convincing punishment. He emphasized that the action taken should be meaningful to the offence. Dr. Gupta stated that the information from States to Centre in respect of Parliament Questions is not readily forthcoming and this results in giving assurances and increases unnecessary correspondence and work of Central Drugs Standard Control Organisation.

While commenting on enforcement of GMPs, almost all the Drugs Controllers stated that as far as granting of new licences is concerned, they are insisting on every firm conforming to GMPs and having its own in-house testing laboratory. However, as far as existing licences are concerned, every effort is being made to persuade licensees to adopt GMPs. It was the consensus feeling that the industry should accept the basic concept of GMP and adopt all these practices which are immediately possible.

The Chairman reiterated that as specified in GMPs separate premises and equipment including separate air handing system should be insisted upon for the manufacture of corticosteroids, sex hormones and B-Lectum antibiotics as contamination of traces of these with other drugs can be hazardous.

After this the agenda items were taken for consideration.

Item No. 1 : Confirmation of the minutes of the last meeting of the Drugs Consultative Committee held on 10th & 11th September, 87.

The minutes of the 25th meeting of the D.C.C. were confirmed.

Item No. 2 : Statement on action taken on the recommendation made by the Drugs Consultative Committee at its last meeting held on 10th & 11th September, 1987.

The action taken on various points arising out of the 25th meeting of the DCC Committee is given in Annexure-I. The salient points were reviewed.

Item No. 3 : Consideration of the report of the sub-committee to examine whether Diagnostic Kits / Reagents should be considered as 'drug'.

The report of the Sub-Committee appointed by the DCC in its 25th meeting under the Chairmanship of Dr.S.N.Saxena, Director, Central Research Institute, Kasauli was considered. It was observed that it is important to control the quality of all diagnostic reagents which are directly concerned with diagnose of diseases. The diagnostic reagents should therefore be licensed under the provisions of Drugs & Cosmetics Act.

Item No. 4 : Report of the Sub-Committee on Testing Laboratories.

The Chairman informed the members that the sub-committee deserves to be congratulated for the excellent work done to produce a good report which will be handy for States and Central Government to plan for creation / upgradation of testing facilities in the country.

Item No. 5 : Manufacture of formulations containing protein hydrolysates, vitamins & minerals etc.

In the last DCC meeting a decision was taken that formulations of feed supplements containing protein hydrolysates, vitamins, minerals etc. should be considered as 'drug'. However, if the manufacturers mention on the label 'Feed Supplement, Not for Medicinal use', he need not take a drug licence.

The manufacturers of Feed Supplements had represented that the words 'Not for Medicinal Use' is a negative indication and should nto be insisted upon. The matter was discussed at length and it was agreed that once the formulation is considered a 'drug', the firm should be asked to take a drug licence and it should comply with all provisions of labeling under Drugs & Cosmetics Rules.

Item No. 6 : Gazette Notification G.S.R. 365 (E) dated 17.3.1989 notifying Sterile Hypodermic Syringes, Sterile Hypodermic needles and IV sets as 'drugs' – Steps to publish the draft Rules.

The Chairman informed that the three devices (Hypodermic needles, syringes and I.V. sets) have been notified as 'drugs' and the manufacturers of these devices should be licensed immediately. Dr. M.A.Patel, Chairman of the sub-committee on medical devices was asked to prepare guidelines / GMPs to be adopted by such units, in consultation with other members of the sub-committee, so that the same are circulated to all State Drugs Controllers for uniform enforcement. Dr. Gupta suggested that representative of 'Isomed' may also be consulted in the matter and this work should be completed in 2 months time.

Item No. 7 : Notification of Sphygmomanometer as drug.

It was agreed that the decision to notify Sphygmomanometer as a 'drug' should be deferred for the time being.

Item No. 8 : Request for changing from calendar year to official year in case of drug licences.

The request for change over from calendar year (January –December) to official year in respect of drug licences was not agreed to by the members of the committee.

Item No. 9 : Recognition of the Degree of Bachelor of Cosmetics Technology under the Drugs & Cosmetics Rules.

The members were of the opinion that the Degree of Bachelor of Cosmetics Technology is a higher qualification than the existing Intermediate (Science) provided under Rule 139. Hence there should be no objection in accepting this suggestion.

Item No. 10 : Need to frame Rules consequent to the amended provisions of Section 26 and 32 of the Drugs & Cosmetics Act.

A Sub-Committee of following members was constituted to suggest the rules which will have to be incorporated in Drugs and Cosmetics Rules to give effect to provisions of Section 26 and Section 32 of the Drugs and Cosmetics Act wherein specific power has been given to consumers and Registered Associations for collecting samples for testing and for filling compliance under the provisions of the Act.

Commissioner, FDA, Gujarat, Drugs Controller, Madhya Pradesh, Drugs Controller, Tamil Nadu, Drugs Controller, Orissa, Drugs Controller, Rajasthan and Dy. Drugs Controller (India), West Zone – Convenor.

Item No. 11 : Floor cleaners and Bathroom cleaners – claiming for disinfectant use.

It was decided that preparation marketed as 'Floor Cleaners', 'Bathroom Cleaners' etc. should be considered as disinfectants and licensed only when the word 'disinfectant' or any other word signifying its use as a disinfectant is mentioned on the label of the product.

Item No. 12 : Need for Rationalisation of B-Complex with Multi-Vitamins formulations.

The members considered this item in detail. In this connection a decision taken by DCC in its 1983 meeting was also considered. It was decided that the following ingredient invariably be present in dose given in Schedule 'V' for a preparation to be claimed as a B-Complex preparation or a multi vitamin preparation.

<u>B-Complex Preparations</u> – Vitamin B1, Vitamin B2, Vitamini B6 Niacinamide and Calcium Penthithenate.

<u>Multi-Vitamin</u> – It was also decided that the contents of these vitamins as per Schedule 'V' should be present in not more than 5 ml. quantity and that in Rule 96(1) (B) iii(a) the words "as multiples thereof" after the words in 5 ml. should be deleted.

Item No. 13 : Formulations common in I.P. and N.F.I. but different in strength.

Chairman explained that where a drug is incorporated in I.P., standards prescribed in I.P. are the only standards under Drugs and Cosmetics Rules.

Item No. 14 : Amendment to the Drugs & Cosmetics Act and the Rules suggested by the State Drugs Controllers in the last meeting of the Drugs Consultative Committee.

After considering the various suggestions received from different Drugs Controllers on amendments to the Drugs and Cosmetics Act and Rules, it was decided that a Sub-Committee consisting of following members should be constituted to examine the suggestions received and recommend the amendments required :-

1. Commissioner, FDA, Maharashtra.
2. Director, Drugs Control, West Bengal.
3. Drugs Controller, Delhi Administration.
4. Drugs Controller, Tamil Nadu.
5. Drugs Controller, Kerala.
6. Drugs Controller, Goa.
7. Drugs Controller, Karnataka.
8. Dy. Drugs Controller, India, South Zone : Convenor.

Item No. 14A : Recommendation of the Sub-Committee for weeding out harmful / irrational formulations.

Five categories of drug formulations about which the sub-committee had earlier examined and opined were recommended by the Drugs Consultative Committee (DCC) and approved by the Drugs Technical Advisory Board (DTAB). However, at the time of initiating notification to prohibit manufacture and sale of formulations belonging to the 5 categories, representations backed by fresh data were received by the Directorate for some of these categories :

(a) The Directorate in consultation with the Ministry of Health and Family Welfare had advised the Chairman of the sub-committee to convene a meeting of T.B. experts to review the category of fixed dose combination of pyrazinamide with other anti-T.B. drugs as the Ministry had received representations.

(b) The Ministry of Law had pointed out that the proposal for banning fixed dose combination of essential oils with alcohol having percentage higher than 12% proof may not be effective unless a decision is taken to exempt or otherwise the tinctures given in Indian Pharmacopoeia.

(c) Representations against proposal to ban addition of chloroform in any liquid preparation continue to be received by the Directorate even after approval of such proposal by DCC on the ground that for bacterial flora of

the environment in the country, there is no suitable substitute to chloroform as a preservative in oral liquid preparations particularly in antacids.

Besides these, another ten items which have been examined by the sub-committee were discussed by the members and their views are as follows:-

(i) **Fixed dose combination of tranquillisers with Analgesics and Antipyretics :**

It was agreed that this combination should be withdrawn as the Expert Committee had recommended that there is no substantial evidence backed by scientific data to administer fixed dose combination of tranquillisers with analgesics – antipyretics.

(ii) **Fixed dose combination of Pyrazinamide with other anti – T.B. drugs :**

The opinion based on fresh review expressed by the T.B. experts about combination of Pyrazinamide with other anit-T.B. drugs and the combinations that may be permitted were agreed to by the members which is as follows :-

	Minimum	**Maximum**
Rifampicin	450 mg	600 mg
INH	300 mg	400 mg
Pyrazinamide	1000 mg	1500 mg

The members agreed that the above combination, within the strengths specified, may be permitted whereas all other combinations may be banned.

(iii) **Fixed dose combination of H_2 Receptor Antagonist (such as Cimetidine, Ranitidine) with other drugs :**

The DCC had agreed to the sub-committee's recommendation to ban fixed dose combination of H_2 Receptor Antagonists with other drugs. In future, in case there is a claim for a new rational formulation under this category, such fixed dose combination should be got approved by the Drugs Controller (India).

(iv) **Fixed dose combination of Essential oils with alcohol having percentage higher than 12% proof :**

Keeping in view of the observations made by the Ministry of Law, that the proposal to ban formulations under this category may not be effective unless a decision is taken to exempt or not tincture formulations given in Indian Pharmacopoeia, the Committee has recommended that the sub-committee should examine formulations falling under this category.

(v) **Addition of Chloroform in any liquid preparation for oral use :**

Keeping in view the opinin expressed by the Ministry of Law, questiong the tenability of a proposal for banning addition of Chloroform in any liquid oral preparation specially when such is allowed in other developed and developing countries and also based on the representations received by the Directorate that considering the bacterial flora of the environment, there is no suitable substituted to Chloroform, particularly in antacid preparation, the DCC has recommended that this category may again be examined by the sub-committee.

(vi) **Fixed dose combination of Ethambutol with INH :**

The committee agreed with the recommendations made by the experts that combination of INH and Ethambutol with following concentration should only be permitted :-

INH	**Ethambutol**
200 mg	600 mg
300 mg	800 mg

(vii) **Pharmaceutical preparations containing more than one anti-histamine :**

The Committee agreed with the opinion expressed by the experts that there is no rational to market formulations containing more than one anti-histamine and such combinations should be banned.

(viii) **Fixed dose combination of anthelmintics with cathartics :**

The DCC has agreed with the opinion expressed by the sub-committee that there is little rationale to combine newer anthelmintics with cathartics, except for those anthelmintics the effect of which is not long lasting and cathartics is required to expel the worms such as combination of cathartics with anthelmintics like Piperazine.

(ix) **Fixed dose combination of Salbutamol / Bronchodilator with other drugs :**

The Committee have agreed to the opinion of the sub-committee that fixed dose combination of Salbutamol or any other bronchodilator with centrally acting anit-tussive or any antihistaminic are not rational. However, formulations containing Salbutamol or any other bronchodilator may contain mucolytic, expectorant provided such preparations do not contain more than one ingredient with identical pharmacologic mode of action.

(x) **Use of animal blood in iron tonics for combating anaemia** :

After a detailed discussion on the item, the Committee decided to refer the item back to the sub-committee for re-examination and give details how modified formulae of hemoglobin tonic can meet the iron requirements.

(xi) **Fixed dose combination of Enzyme preparations :**

The DCC has agreed to the opinion of the sub-committee that (i) addition of laxatives in enzyme preparations is not rational, (ii) addition of antispasmodic drugs in enzyme preparations is not rational and (iii) the reports of ongoing clinical trials of enzyme preparations containing intestinal sedatives should be reviewed by the sub-committee after trials are completed and place its views before the Drugs Consultative Committee.

Notwithstanding the above recommendations, all enzyme preparations must be proved for its stability, compatibility and therapeutic efficacy.

(xii) **Fixed dose combination of Ibuprofen with Narcotic / Non –narcotic analgesics :**

After discussion the Committee has recommended that the time is not yet opportune for banning such combinations and therefore, the consideration of the matter to be deferred for the time being as the experts have recommended carrying out retrospective and prospective clinical trials to confirm the theoretical rational that exists for administrating anti-inflammatory drugs with analgesics in painful inflammatory conditions.

(xiii) **Fixed dose combination of Metoc lopramide with Paracetamol :**

The Committee agreed with the recommendation made by the experts that the fixed dose combinations of Metoc lopramide with Paracetamold or with any analgesic be banned as the combination may cause extrapyramidal side effects.

(xiv) **Patent and proprietary preparations for systemic relief of cough :**

The Committee agreed with the recommendation made by the experts that cough preparations should be labeled as per one of the three following categories and it should contain the ingredients within the proportion indicated against each per dose :-

(a) **Dry cough or productive cough with scanty sputum or allegic cough :**

Formulations may contain a centrally active anti-tussive or centrally acting anti-tussive with one or more drugs which complement its action peripherally by different mechanisms along the path of the cough reflex viz. anti-histamines, decongestants, expectorants.

(b) **Productive cough with thick viscid and tenacious sputum :**

It should not contain centrally active anti-tussive or an anthihistamine with high atropine like activity. They may contain on or more ingredients which act peripherally by different mechanisms to facilitate the liquefaction and expulsion of sputum viz. expectorants, mucolytics, decongestants, antihistamines with low atropine like activity.

(c) **Cough associated with Asthma :**

The preparations claiming to combat cough associated with asthma should not contain centrally anti-tussive or an anthihistamine. These preparations may contain ingredients which produce bronchodilatation and liquefaction of sputum viz. bronchodilators, expectorants, and mucolytics.

For each of the above 3 types of cough preparation, such preparation should not contain more than one ingredient with an identical mode of action and each ingredient should be present in an acceptable dose range. The recommendation with regard to acceptable dose of centrally acting anti-tussive antihistamine, decongestants, expectorants, bronchodilators are annexed.

The prescribing information for the above 3 categories of cough preparation should give cautionary statement wherever necessary viz. caution against drowsiness or car driving or handling machinery for antihistamines; caution of their use in patients with hypertension or coronary heart disease for decongestants, etc.

(xv) **Tonic preparations :**

The Committee agreed with the recommendation made by the experts that addition of Glycerophosphates / other phosphates or any other .....

and alcohol should not be permitted as there is no rationality for inclusion of these in such preparations.

The Committee further agreed with the recommendation that tonic preparation should contain vitamins either in prophylactic or therapeutic doses as given in Schedule 'V' to the Drugs and Cosmetics Rules.

COUGH FORMULATIONS

Recommendations on Ingredients and Acceptable Doses.

Name of Drug	Acceptable Qty/Audit Dose (mg)	Comments
(1)	(2)	(3)
Class / Mode of Action : CENTRALLY ACTING ANTITUSSIVES		
Codeine	10.0 – 20.0	
Dextromethorphan	10.0 – 30.0	
Dihydrocodeinone	5.0 – 10.0	Syn : Hydrocodone
Ethylmorphine	6.0 – 12.0	
Noscapine	15.0 – 30.0	Weak bronchodilator, Stimulates respiration.
Oxeladin	20.0 – 40.0	
Pholcodine	5.0 – 15.0	
Pipazethate	20.0 – 40.0	
Class / Mode of Action : ANTIHISTAMINE		
Azatadine	1.0 – 2.0	
Bamipine	10.0 – 20.0	
Carbinoxamine	4.0 – 8.0	High atropine-like activity.
Chlorpheniramine	2.0 – 4.0	
Dexchlorpheniramine	2.0 – 4.0	
Diphenhydramine	12.5 – 25.0	High atropine-like activity.
Diphenylpyraline	2.5 – 5.0	
Isothipendyl	4.0 – 8.0	
Mepyramine	12.5 – 25.0	

Methdilazine	2.0 – 4.0	High atropine-like activity.
Phenindamine	10.0 – 20.0	
Pheniramine	12.5 – 25.0	
Promethazine	12.5 – 25.0	High atropine-like activity.
Triprolidine	2.5 – 5.0	
Class / Mode of Action : DECONGESTANTS		
Ephedrine	5.0 – 15.0	
Phenylephrine	5.0 – 10.0	
Phenylpropanolamine	5.0 – 10.0	
Pseudoephedrine	30.0 – 60.0	
Class / Mode of Action : EXPECTORANTS		
Ammonium Chloride	100 – 200.0	2-4% w/v or 20-40 mg/ml
Guaiphenesin	50.0 – 200.0	Syn:Glyceryl Guaiacolate
Potassium guaiacol Sulphonate	50.0 – 100.0	
Sodium Citrate	100.0 – 200.0	2-4% w/v or 20.40 mg/ml
Tarpin hydrate	5.0 – 10.0	
Class / Mode of Action : BRONCHODILANTORS		
Aminophylline	100.0 – 200.0	
Hydroxyathyltheophylline	100.0 – 200.0	Syn : Etophylline
Isoprenaline	10.0 – 20.0	
Orciprenaline	2.5 – 5.0	
Salbutamol	2.0 – 4.0	Syn : Albuterol
Terbutaline	2.5 – 5.0	
Theophylline	100.0 – 200.0	
Class / Mode of Action : MUCOLYTICS		
Bromhexine	8.0 – 16.0	
Iodide (Na, K, Ca)	100.0 – 300.0	
Syrup Vasaka	2.0 – 4.0	Dose in ml
Vasaka liquid extract	1.0 – 2.0	Dose in ml

Item No. 15 : Whether Chlorine tablet falls under the definition of Drug in Secion 3(b) (ii) of the Drugs & Cosmetics Act, 1940.

It was agreed that chlorine tablets as well as liquid chlorine / chlorine solutions used for disinfection of water is a 'drug' and both the items should be licensed under Drugs & Cosmetics Rules. It was further agreed that it is already covered under the definition of the 'drug' and there is no necessity for it being notified as a 'drug'.

Item No. 16 : I.P. 1985 – Test of uniformity of contents in certain dosage forms where the active ingredients is 10 mg or less per tablet.

The Committee did not agree with the recommendation that uniformity of contents should be made applicable for patent and proprietary medicines as the uniformity of contents is more relevant for a single ingredient drug only.

Item No. 17 : Amendment to part XII-B of the Drugs & Cosmetics Rules and monograph of Whole Human Blood in B.P. with regard to date of expiry, when CPDA solution is used as anti-coagulant.

The Committee agreed that the life period of whole human blood collected in CPDA anti-coagulant solution be extended to 35 days. The members were informed that necessary amendment / corrigendum would be carried out / issued in Drugs & Cosmetics Rules and Indian Pharmacopoeia respectively.

Item No. 18 : Amendment to Section 27A(i) of the Drugs & Cosmetics Act, 1940.

The Chairman stated that there appears to be a printing error and necessary steps will be taken to get corrigendum issued.

Item No. 19 : Amendment of Section 18 of the Drugs & Cosmetics Act 1940.

While considering the question of amending Section 18 of the Act, the Drugs Controllers Delhi, Madhya Pradesh and Commissioner, F.D.A. Maharashtra suggested that Section should be amended. During discussion it was proposed that 'comma' should be added after the word 'Stock'. Chairman stated that the original Gazette notification will be checked and if a 'comma' is already not there, as suggested in the item, necessary amendment will be carried out.

Item No. 20 : Amendment to Section 22(2A) of the Drugs & Cosmetics Act 1940 read with Rules 55A of the Drugs & Cosmetics Rules, 1945.

Commissioner, F.D.A., Maharashtra suggested to enhance the period of return of the documents seized by the inspector from twenty days to forty five days. The Chairman stated that the matter will be examined. The Drugs Controller (Tamil Nadu) was, however, requested to furnish a copy of the relevant judgement which has been delivered concerning the matter.

Item No. 21 : Whether animal meant for veterinary use is to be considered a 'drug'.

The Chairman informed the members that this item has been discussed in earlier meetings also. During discussion Drugs Controller (Tamil Nadu) stated that when a drug is administered though a 'feed', it may be considered whether the 'feed' could be declared as a drug. It was decided by the Committee that ready-mixed animal – feed, containing vitamins or other drugs in small proportions, may not be considered drugs, however, animal feed premixes containing drugs should be considered 'drugs' and be licensed under Drugs and Cosmetics Rules.

Item No. 22 : Cosideration of the question of prosecution of manufacturer of one State (for manufacturing and supplying sub-standard drugs in another State by not following the earlier D.C.C. guidelines.

The Chairman desired that the matter regarding action on reports of sub-standard drugs need to be decided on top priority by the State Drugs Control Authorities. The Chairman further exhorted the members to evolve a mutual consensus in the matter keeping in view the guidelines already issued by the sub-committee constituted under XXII D.C.C. meeting. During discussion Commissioner F.D.A. Maharashtra stated that the mater concerning acion on sub-standard drugs should be viewed seriously and strict action should be taken against the defaulters. The members agreed that the guidelines approved in 22nd D.C.C. Meeting should be adhered to as far as possible. However, it should be left at the discretion of the concerned Drugs Controller to file a prosecution in his State or to refer the case to the Drugs Controller of the manufacturing State as circumstances warranted. That every Drugs Controller should invariably supply the information sought by other Drugs Controller in case a prosecution is to be launched irrespective of whether the Drugs Controller of manufacturing State agrees to the decision of the Drugs Controller where the sample has been drawn to launch prosecutions.

Item No. 23 : Inclusion of certain Rules in Part XVA of the Drugs & Cosmetics Rules 1945 for carrying out tests by approved laboratories for drugs etc. prescribed in the concerned pharmacopoeias before issuing any test report.

After a detailed discussion there was a consensus of view that approving authorities have the power to withdraw approval granted to a testing laboratory.

Item No. 24 : Definition of cool place in I.P. vis-à-vis Schedule 'P' of the Drugs & Cosmetics Rules.

The Chairman explained that I.P. definition for a cool place is 8 degree C to 25 degree C and not 8 degree C to 20 degree C as mentioned in the Agenda item. Therefore, there is not much variation between the definition of cool place in I.P. and Schedule 'P' and hence no action is necessary.

Item No. 25 : Need to restrict multidose vials to a total volume of injection sufficient to permit the withdrawal of not more than 10 doses and to include Immunological products.

The Committee agreed that the Drugs Controller should stick to the I.P. '85 recommendation that multidose injectable containers should not contain more than 10 doses. All the State Drug Controllers agreed that they should strictly adhere to this decision. It was, however, stated that the multidose injectable containers having more than 10 doses should be stopped.

Item No. 26 : Restriction to manufacture Patent and Propreitary medicines of the same strength under the same trade name under different colours and flavours.

While considering the item it was decided that guidelines should be laid. Under the circumstances, a sub-committee with following members was constituted to examine the matter :-

Commissioner, F.D.A. Maharashtra	-	Chairman
Director, Drugs Control, West Bengal	-	Member
Drugs Controller, Bihar	-	Member
Drugs Controller, Orissa	-	Member
Dy. Drugs Controller (I), East Zone	-	Convenor

It was decided that sub-committee should give its recommendation within three months time.

Item No. 27 : Date of expiry of finished formulations, beyond the date of expiry of bulk drugs.

After discussion it was agreed to by the members that a finished drug cannot be permitted to have an expiry beyond that of the bulk drug. The Committee also agreed that this decision should also be made applicable to narcotics.

Item No. 28 : Regarding coating of N.F.I. formulations.

Chairman explained that N.F.I. is not a book of standards and therefore tablets with N.F.I. composition can be coated.

Item No. 29 : Printing of detailed particulars on strip packing under Rule 96.

It was decided after discussion by the members that the strips in which tablets are packed should bear all the labeling requirements printed on them even if they are given in catch-covers.

Item No. 30 : Consideration whether an approved laboratory in Form 37 can refer samples to another laboratory also approved under Form 37 to carry out tests for which the former does not have facilities.

It was agreed by the members that there is no justification for one approved testing laboratory to incorporate in the test report issued by it the results of tests got done from another approved testing laboratory. Each testing laboratory should issue its own report on a sample of drug which had been forwarded to it by the manufacturer / supplier, etc.

Item No. 31 : Need to check correctness of setting time of plaster of Paris Bandages B.P. '88.

Chairman stated that as the issued raised pertains to a standard given in a foreign pharmacopoeia, no action can be taken in the matter immediately. However, necessary clarification will be sought from British Pharmacopoeia Commission.

Item No. 32 : Regarding formation of a Central Formulation Bank at the level of Drugs Controller (India), New Delhi.

Chairman stated that this aspect has already been covered after incorporation of new definition of a 'New Drug' in the amended rules. A State Drug Controller can no more grant permission for manufacture of a new combination even of existing drugs. Necessary permission of licensing authority appointed under rule 21 will have to be obtained by the

manufacturer before a State Drug Controller can grant permission for manufacture of a new combination.

Item No. 33 : Displaying of photograph of qualified person on retail / wholesale licences.

The Chairman stated that for requiring a photograph to be affixed on retail / wholesale licences of qualified persons the matter could be taken up with the Pharmacy Council by the State Drugs Controllers to find a suitable solution.

Item No. 34 : Prior sanction of the controlling authority to launch prosecution by an 'Inspector' under the Drugs & Cosmetics Act and Rules.

There was consensus of views among the members that there is no necessity for any amendment requiring an 'Inspector' to obtain prior sanction of controlling authority before launching prosecutions under Drugs and Cosmetics Rules. The problem can be solved by issuing suitable administrative orders as there is already a provision in rule 51 whereby a controlling authority can exercise necessary control over activities of a Drugs Inspectors.

Item No. 35 : Quality control of 'New Drug'.

Chairman stated that efforts will be made to circulate to all State Drug Controllers the methods of analysis, standards, etc. as and when a 'New Drug' permission is granted to the manufacturer by the Drugs Controller (India).

Item No. 36 : Restrictions for grant of retail / wholesale licences.

The members agreed that granting of retail and wholesale licences be restricted only to qualified and competent persons who can be approved under the Drugs and Cosmetics Rules. During discussion many members pointed out that presently the drugs are no more being sold by vendors and therefore, the relevant provisions in the Drugs and Cosmetics Rules should be deleted. It was decided that this matter will also be examined by the sub-committee appointed under Item No. 14.

Item No. 37 : Need to limit the numer of amendments in the Drugs & Cosmetics Act & Rules thereunder.

Chairman stated that as far as possible efforts will be made to publish amendments to Drugs and Cosmetics Rules in a consolidated way.

Item No. 38 : Need for amending rules 69-A of the Drugs and Cosmetics Rules 1945.

Chairman stated that due to oversight necessary amendment was left in the proviso to rule 69-A for changing the fee from Rs.100/- to Rs.200/- and this will be amended.

Item No. 39 : Compounding of offences.

Chairman stated that the matter of amending the Drugs and Cosmetics Act to include compounding of offences should be examined by the sub-committee mentioned under Item No. 14.

Item No. 40 : Return of records registers and other documents under Section 22(2A) of the Drugs and Cosmetics Act 1945.

Since the Drugs Controller, Tamil Nadu had not furnished a copy of the High Court decision in the matter, the item could not be discussed.

Item No. 41 : Introduction of separate licence for Blood Banks.

Chairman informed the members that the draft of amended rules concerning blood banks is in the process of being published. All members were requested to give their comments on the draft rules as soon as these are published.

Item No. 42 : Framing of Fresh Guidelines for taking action against manufacturers located in other States.

It is already discussed under Item No. 22.

Item No. 43 : Veterinary drugs are omitted from Schedule 'V', especially in case of standards for patent or proprietary medicines, containing vitamins : Schedule 'V' is required to be amended for this purpose.

Item No. 44 : Suggestion to amend entry No.2 of Schedule V, viz. standards for patent or proprietary medicines containing vitamins to include veterinary use.

Item No. 45 : Suggestion to amend rule 65(5) (1) of the Drugs & Cosmetics Rules in pursuance of the amendment to Rule 64(2) which required premises holding licences in form 20B and 21B are required to be in charge of a 'competent person'.

It was decided that the matter concerning these items will be considered by the sub-committee appointed under Item No. 14.

Item No. 46 : Suggestion for amendment in the Drugs and Cosmetics Rules making it mandatory for sale of cosmetics preparation.

It was decided that it is not necessary to incorporate provisions in Drugs and Cosmetics Rules to have a sales licence for cosmetics because consensus of the views expressed was that it will be extremely difficult to exercise control over such premises due to paucity of inspectorate staff.

Item No. 47 : Consideration of a proposal for dissipating information on products declared as not of standard quality of a manufacturer of particular state to another State Drugs Controller in time bound way to carry out effective Drug recalls.

Already discussed under Item No. 22.

Item No. 48 : Suggestion for amendment of Rule 64 of Drugs & Cosmetics Rules regarding space for the premises for grant of wholesale / retail licence.

After detailed discussion it was decided that area can not be prescribed for retail licences. It should, however, be left at the discretion of the licensing authority at present.

Item No. 49 : Suggestion to separate wholesale business of drugs from retail sale.

This was not agreed as it was considered impractical.

Item No. 50 : Suggestion to amend Schedule 'M'.

The matter was discussed. It was decided that Schedule 'M' should be suitably amended to incorporate separate requirements for 'internal use' and 'external use' preparations.

Item No. 51 : Proposal for amendment of Rule 71(i) an d76(i).

The proposed rules 71 and 76 may be suitably amended providing a proviso in each of the Rule fo rthe Drugs Inspectors, who have gained experience for not less than 3 years in the inspection of firms manufacturing drugs under Schedule C and C1, be also considered s "competent technical person" under Rules 71 and 76. The Committee did not agree to the proposal.

Item No. 52 : Amendment of Section 3(b) of the Drugs and Cosmetics Act, 1940 regarding patent or proprietary medicines.

Dr. Misra, Advisor, Indian System of Medicines informed the members that it is not feasible to manufacture Ayurvedic eye preparations under

conditions analogus to Modern System of Medicines because these preparations are being manufactured for sale since a long time.

While participating in the discussion, Drugs Controller, Delhi Administration and Asstt. Drugs Controller, Rajasthan stated that these preparations must be manufactured as per the conditions laid down for parenteral preparations because these preparations have to comply with test for sterility. Keeping this in view licences in Form 28 are being issued to the manufacturers for this category of ayurvedic preparation. Drugs Controller, Tamil Nadu, however, was of the opinion that an expert in Ayurveda may be consulted prior to grant of licence on Form 28 for this category of Ayurvedic preparation.

It was, therefore, agreed by the members that the matter should be referred to Ayurvedic Drugs Consultative Committee for consideration.

Item No. 53 : Suggestion to amend Form 34 for Analysis of Cosmetics.

Chairman informed the members that as far as matter concerning amendment of Form 34 and regarding issue of certificate of test or analysis of cosmetics is concerned, it is under consideration of a group of Govt. Analysts already constituted for the purpose.

Item No. 54 : Suggestion for provision of existing Schedule of fees under the Drugs and Cosmetics Rules, 1945.

Chairman informed the members that the notification enhancing licence fees has been struck down as ultra vires by Patna High Court. Central Government has already filed an appeal and the matter is sub-judice. Individual State Government, they so desire, may consider to amend the relevant Rules under powers vested with them as the subject of Drugs Control is in the concurrent list of the constitution.

Item No. 55 : Suggestion to prohibit the use of Chloroform in Pharmaceutical preparations.

The matter has already been considered under Item No. 14-A.

Item No. 56 : Blood Banks.

Already discussed.

Item No. 57 : Publication of uptodate Drugs & Cosmetics Act & Rules thereunder.

As far as publication of uptodate Drugs and Cosmetics Act and Rules thereunder are concerned, the Chairman stated that it will be done in course of time.

Item No. 58 : Mushroom Growth of Pharmacies.

While discussing the issue that Rule 64 of the Drugs & Cosmetics Rules, 1945 should be amended to prevent proliferation of Chemists and Druggists, the members agreed that the matter may be referred to the sub-committee appointed under Item No. 14.

Item No. 59 : Amendment concerning Drugs and Magic Remedies (O.A.) Act and Drugs & Cosmetics Act.

The Chairman informed the members that the matter concerning updating of Schedule J is already under active consideration of the sub-committee appointed by DTAB.

Item No. 60 : Drugs bearing hospital markings.

While discussing the matter that Rule 65(18) of the Drugs and Cosmetics Rules, 1945 should be amended to stop stocking of Drugs bearing 'Hospital markings' by the licensed dealer, the members agreed that the matter may be referred to the sub-committee appointed under Item No. 14.

Item No. 61 : Competent Technical Staff.

While discussing the matter that Rule 76 of the Drugs and Cosmetics Rules should be so amended that graduate in Vet. Science can be permitted to undertake manufacture of Vet. Drugs on licences granted in Form 28, the members agreed that the matter may be referred to the sub-committee appointed under Item No. 14.

Item No. 62 : Cold storage facilities.

During discussion, Drugs Controller, Tamil Nadu informed that preparations like Sera / Vaccines / Insuline are being chiefly manufactured in State of Maharashtra and are then being transported to other States of the country for the purpose of distribution. He felt that these preparations are not being transported under proper cold storage system. The Chairman stated that there should be no relaxation as regard providing proper facilities for drugs during transport. He desired that all State Drugs Controllers should ensure that the manufacturers provide proper storage facilities during transport. He informed the members that vans with refrigeration facilities are available and so there should be no difficulty in its enforcement.

Item No. 63 : Sampling procedures.

The members felt that clear cut provisions are not available under the existing Drugs and Cosmetics Act, 1940 as to whom the sealed portion of the samples drug should be got sent viz. the manufacturer or the person whose name has been disclosed by the dealer.

In lieu of these provisions, the members stated that cases of prosecutions launched by the State Drugs Control authorities against the manufacturere have been lost for the reason that the manufacturer whose name was found labeled on the sample drug, was not given any opportunity either to examine the sealed portion of the sampled drug or to comment on the copy of the test report. The Chairman proposed that the matter may be referred to the sub-committee appointed under Item No.14.

Item No. 64 : Protection under Sec.19(3) of Drugs and Cosmetics Act.

The members stated that the 'pleas' noted under Sec. 19(3) of the Drugs and Cosmetics Act 1940 affords opportunity of defence to all the persons other than the manufacturers and their agents. According to the present provisions of 'pleas' it appears as if even unlicenced dealers can not be prosecuted. The Chairman agreed with the members that the matter may be examined by the sub-committee under Item No.14.

Item No. 65 Manufacture for sale or distribution of Drugs / Class of Drugs not benig of standard quality.

Chairman explained that this is only a special provision under the Drugs & Cosmetics Act 1940 to enable Central Government to meet the emergency situations. The Chairman felt that to his knowledge the Central Government had not used the power available under the Section even once. The members agreed that no action at present is necessary in the matter.

Item No. 66 : Narcotic Drugs and Psychotropic Substances Act and Rules made thereunder.

While discussing Rule 53 of the Narcotics Drugs and Psychotropic Substances Act, Chairman informed the members that Ministry of Finance had already issued administrative orders removing Alprazolam from the banned list. The New Drug Permission was only granted after consulting the Ministry of Finance.

Item No. 67 : N.F.I. Drugs.

The matter may be referred to the sub-committee under Item 14 for examination.

Item No. 68 : Common laboratories.

While deciding the issue regarding Testing Laboratory, jointly owned by 2 or more manufacturing firms, the Chairman stated that as per earlier decision of D.C.C., the arrangement of common laboratories fro manufacture of 'Eucalyptus Oil' and 'surgical dressings' can be permitted to continue.

Item No. 69 : Clause under Rule 64(2) of the Drugs and Cosmetics Rules 1945 should be incorporated similar to clauses available under 'Pre-conditions for grant of all types of Drugs Manufacturing Licences'.

Regarding incorporation of provisions for empowering licensing authority to refuse to grant or renew various manufacturing licences under the Drugs and Cosmetics Rules 1945, the members agreed that the matter may be referred to sub-committee appointed under Item No. 14.

Item No. 70 : Suggestion regarding incorporation of certain provision under Rule 65 (15) (C) regarding "Qualified Person".

The Chairman informed the members that no action is possible to incorporate any provision under Rule 65(15) (C) to define the "qualified person" because the Pharmacy Council of India had repeatedly examined the matter and did not agree to the suggestion. The Council is further of the view that adequate 'qualified pharmacists' are available to the country as about 800 new pharmacists are coming out of the educational institutions every year.

Item No. 71 : Whether "Blister-packing Facility" should be allowed under loan licence at a common place.

It was decided that the matter has already been considered and a decision taken by the Committee appointed to consider constitution of Loan Licence System.

Item No. 72 : Training of officers holding rank of Assistant Directors, Deputy Directors etc. in the State Drug Control Authorities under the Drug Inspectors' Training Scheme.

On training of officers, other than the Drug Inspectos, the Chairman explained that besides Drug Inspectors other officers can also be deputed for the training which is presently being conducted by the Central Drugs Standard Control Organisation.

Item No. 73 : 'Potentisation from bulk Potency'.

While considering the question of the space that should be examined under Section 'M' of the Drugs and Cosmetics Rules 1945, Dr. Augustine, Deputy Advisor (Homoeopathy), explained that a large number of bulk ppotencies have to be stored by licencees holding licences for disposing of potencies under the circumstances no concession should be given about space.

Item No. 74 : Grant of licences for manufacture for sale of Ayurvedic / Siddha / Unani Drugs.

While considering grant of licences for manufacture for sale of Ayurvedic / Siddha / Unani Drugs in form 25-D, Rule 157 as well as on points on which the experts should be consulted, the members agreed with Dr. Misra, Advisor (Ayurveda) that an expert be consulted on the following points :-

1. Whether the drugs applied for are Ayurvedic.
2. To ascertain that method of manufacture proposed to be adopted is as per Ayurvedic principles and as prescribed in books listed in Schedule I.

Item No. 75 : Amendment of Form 13-A for Ayurvedic, Siddha and Unani Medicines.

Regarding amendment of certificates of test or analysis by Govt. Analyst on Form 13-A, the members agreed that the proposed amendment will not serve any purpose because Standards have not yet been prescribed for most of the Ayurvedic drugs.

Item No. 76 : To consider in making amendments in the Existing Drugs and Cosmetics Rules, 1945 making it mandatory for sales premises to take out retail / wholesale licences as the case may be for Ayurvedic Drugs.

While considering amendments under Drugs and Cosmetics Rules 1945 to make it mandatory for the sales premises to take out licences for sale of Ayurvedic Drugs, the members agreed that it was premature to insist on sales licences for Ayurvedic drugs. Besides, it will not be possible to enforce it due to paucity of inspectorate staff.

Item No. 77 : Competent Technical Staff for Ayurvedic Drugs.

As far as appointment of competent technical staff for manufacture of Ayurvedic preparations (like tablets, capsules, ointments etc.) is concerned, Dr. Misra explained that subject of Ayurvedic Pharmacy is being taught to Ayurvedic Graduates and they are competent enough to supervise the manufacture of such Ayurvedic preparations. Thus it was decided that no amendment to Rule 157 is required.

Item No. 78 : Requirement under Schedule 'T' (Ayurvedic Drugs).

It was decided by the Committee that same premises, machinery equipment etc. should not be permitted for manufacture of Ayurvedic drugs and allopathic drugs as there may be chances of intermixing of these drugs during the course of manufacture.

Item No. 79 : Whether combinations of Homoeopathic Drugs are to be treated as 'New Drugs'.

The Chairman stated State Drugs Controllers should furnish a list of Homoeopathic combinations, which according to them were irrational and needed weeding out. He added that 'Homoeopathic shampoo' should not be permitted as a Homoeopathic drug. Further Homoeopathic Eye drops need be licenced on Form 28 till a new form is drafted for this purpose.

ADDITIONAL POINTS :

Item No. 80 :

Drugs Controller, Kerala raised a point that the Ayurvedic book 'Rastantra Sara Prayago Samraha' included in Schedule I to the Drugs and Cosmetics Act contained some allopathic drugs such as Iodine, Panicillin, etc.

Dr. Misra, Advisor (Ayurvedic) explained that this book has two parts. Only the second part included these allopathic drugs. He stated that second part of the book is not a book of standards as per Schedule I.

Item No. 81 :

A point was raised that the word 'approved' in 'entry 2' of the licence in Form 25 before the words 'expert staff' should be added as in the case in Form-28 for the reason that an anomaly might result in names of even unapproved staff being entered on licence in Form 25. Therefore a suitable amendment was sought to be made.

Members felt tha tthere is substance in the point raised. The Committee decided that the point should be considered by the sub-committee appointed under Item No.14.

During the afternoon of 15.9.89, representatives of the O.P.P.I., I.D.M.A., N.I.S.S.M.A. also attended the meeting.

One member of each of the three associations made following points on difficulties being faced by their members.

Shri Aggarwal President OPPI

1) There was a need to make a distinction between 'substandard' and a 'spurious' drug. Further defects found in sub-standard drugs should be categorized as per seriousness of defect. Keeping in view the nature of defects, action to be taken should be accordingly categorized.

2) Defects develop in drugs due to different climatic conditions in the country and improper transport and storage. Therefore, conclusion on quality of a batch should not be drawn on the basis of testing of one or two packs.

Shri N. I. Gandhi President IDMA

1) Due to acute space problem faced by units situated in Metropolitan areas, a committee of representatives from manufacturers and Drug Control Officers should be formed to exmine provisions of Schedule 'M'.

On this point Chairman observed that the space specified in amended Scheule 'M' for different sections is almost same as that in earlier Schedule 'M' and therefore this cannot be considered a problem in implementation of G.M.Ps.

2) Prosecutions against a Manufacturer should be launched only by the Drugs Control Administration of the State where a manufacturer is located and not in th States where the sample was found to be not of standard quality.

Shri V. K. Jain President N.I.S.S.D.M.A.

1) State Drugs Control authorities should investigate the reasons for shortage of drugs and not only monitor shortage of drugs.

2) Chloroform is a very good bactericide in alkaline medium and should be permitted in liquid preparations like antacids. That data in support of this view is available and can be produced if required.

3) Samples collected for testing are often tested even 1 year after collection. Further the conditions under which the samples are stored are not known.

4) Hospitals do not have adequate storage facilities. Prosecutions are being launched even on samples which are collected from the hospitals which have in adequate storage facilities.

5) While publishing substandard drugs, full facts about the drug should be given to avoid undue publicity. Giving only name and batch number does not give any idea about nature of defects and hazard involved.

6) A manufacturer should not be prosecuted for one substandard batch at more than one place.

7) Sponsoring authorities should recommend to the concerned authorities that uninterrupted power supply should be made available to pharmaceutical units.

Chairman made following observations in respect of the points raised by the Associations' Representatives :-

1) Drugs Control Administration are answerable to public. Action has to b e taken on every drug reported to be not of standard quality and action taken has to be convincing and relevant to the cause of defect. He informed that due to paucity of Inspectorate Staff and testing facilities, samples are not being collected in sufficient number and hence the chances of substandard drugs being detected are less.

2) The G.M.Ps. are now codified and therefore industry must implement G.M.Ps. in proper spirit.

3) It cannot be agreed that prosecutions should be launched in the State where the manufacturer is located.

In the afternoon of 15.9.89 a lecture-cum-demonstration was given by the officers of C M C Limited (Computer Maintenance Corportation) on utilization of computers for storage and transfer of information by Drugs Control Administrations. They also elaborated on how their company can assist in setting up computer system and interlinking of computers from different States with each other and centre for quick transfer of information. Members showed much interest and all were of unanimous opinion that provisions of computer and interlinking will go a long way in facing the problem of storing and transmission of information within an organization or between the organizations.

Meeting ended with a vote of thanks to the Chair.

Annexure – I
(Item no. 2 of the 26th meeting)

Statement showing the action taken on the decisions taken at the 25th Meeting of the Drugs Consultative Committee held in New Delhi on the 10th & 11th September 1987.

NO.	SUBJECT DISCUSSED	DECISION TAKEN	ACTION TAKEN
(1)	(2)	(3)	(4)
1.	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.	The proposal for inclusion of 7 more I.S. specifications for finished cosmetics under the Drugs & Cosmetics Rules was considered by the DTAB. The draft amendment to the Drugs & Cosmetics Rules has been sent to the Ministry of Health.
2.	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 decided that the matter of packing of drugs should be exempted from the provisions of the Weight and Measures Act 1977.	The decision taken by the committee was communicated to the concerned authorities vide letter No. 15-14/85-DC dated 21/3/1988.
3.	Use of approved colour mixtures – manner of labeling	The committee did not agree to giving any exemption for showing name of the colours on the label of the drugs. It was also decided that mixing of different colours should not be permitted.	The All India Manufacturers Organisation has been informed of the decision of the committee vide letter No. 15-68/85-DC dated 21/3/1988.
4.	Request for insisting for the sale of Oxytocin Injections for Veterinary use against prescription of a Registered	Large Scale misuse of Oxytocin by the milkmen was voiced by many members. After detailed discussion the guidelines to tackled this problem was finalised.	Guidelines finalised by the committee was circulated to all State Drugs Controllers alongwith important decision of the meeting vide letter No. X 19013/1/88-D dated

	Veterinary Medical Practitioner.		19/4/88.
5.	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.	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.	The matter was discussed in the meeting of the DTAB. A draft amendment to the Drugs & Cosmetics Rules has been sent to the Ministry of Health for further action.
6.	Sale of life-saving drugs in Polythene bags	The use of Polythene bags for marketing batlets and capsules of drugs was not ethical and should be stopped.	The decision of the meeting was communicate to all State Drugs Controllers alongwith important decisions of the meeting vide letter No. X 19013/1/88-D dated 19/4/88.
7.	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.	ORS is being included in I.P. has been requested to draft out a suitable monograph based on BP88.
8.	Status of Animal feed supplements containing Antibiotics / Antibacterial Vitamins.	Item to be discussed in the next meeting after the Drugs Controller, Karnataka will collect more data about the position obtaining in foreign country.	The Drugs Controller Karnataka was requested to collect more data from foreign country before bringing this item for consideration.
9.	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.	Under consideration of I.P. Committee.

10.	Notification of Medical devices such as IV sets blood transfusion sets and hypodermic needles as drugs.	The necessary notification in this regard will be issued.	Ministry of Health have issued notification vide GSR 365 (E) dated 17/3/89 declaring three medical devices as drugs.
11.	Containers and delivery systems for eye drops	The specifications of "Itone" of M/s. Dey's Medical Stores packing could be adopted by others. Additional Director, Drugs Control, West Bengal promised to get the specifications from the manufacturer and make them available to the Committee.	The Director of Drugs Control, West Bengal was requested to obtain the specification from the firm.
12.	Water for Injection-Modificaiton of Monograph.	It was recommended that item may be forwarded to the Indian Pharmacopoeia Committee for its consideration.	Under consideration of I.P. Committee.
13.	Expiry date for bulk drugs	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.	Decision of the meeting was communicated alongwith important decision taken by committee to all State Drugs Controllers vide letter no. X 19013/1/88-D dated 19/4/88.
14.	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.	Comprehensive draft amendment on Blood Bank has been proposed in consultation with Ministry of Law which will be published for comments.
15.	Prohibition for the manufacture for sale of saccharin containing formulations for paediatric use.	The committee reiterated the earlier decision that preparations requiring syrup shall not contain Saccharin. It was further decided to ascertain the present position for paediatric preparations from the FDA, USA.	The Food & Drug Administration USA was consulted. It is observed from the reply received that there is no ban on use of Saccharin in Food Drugs & Cosmetics. All State Drugs Controllers have been informed not to take action on earlier decision till final decision is taken.
16.	Return of records, registers or	It was decided to examine this matter after	This Directorate has requested the Drugs

	other documents Section 22 (2A) to be amended.	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 relevant judgement.	Controller, Tamil Nadu vide letter No. X 19013/3/87-D dated 7/3/88 to furnish the requisite information.
17.	Proposal for amendment of Section 27(b), 27(c) and 27(d) of the Drugs & Cosmetics Act.	It was decided to examine the matter in the light of the letter of the Secretary of Andhra Pradesh Government.	The matter is being examined in consultation with the Ministry of Law. Ministry of Health have written to the Health Secretary Govt. of Andhra Pradesh asking for further enformation as desired by Ministry of Law.
18.	Availability of drugs in rural areas.	It was agreed that the Drugs Controller, Madhya Pradesh will send a detailed proposal with justification so that it could be considered further.	This Directorate has requested the Drugs Controller, Madhya Pradesh vide letter No. X 19013/1/88-D dated 3/3/88 to send detailed proposal for examination.
19.	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 is decided to refer the matter to the Indian Pharmacopoeia committee.	Under consideration of I.P. Committee.
20.	Consideration of a question as to whether product permission for Chloramphenicol Inj. In liquid and powder forms be granted for otherwise.	It is decided to refer the matter to the Indian Pharmacopoeia committee.	Referred to I.P. Committee for its consideration.