MINUTES OF THE 31st MEETING OF THE DRUGS CONSULTATIVE COMMITTEE HELD ON 21st & 22nd AUGUST, 1997

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The items on the agenda were then taken for consideration.

A. **Confirmation of the minutes of the 30th DCC held on 7th September, 1995.**

The minutes were confirmed.

B. **Consideration of the Report of Sub-Committee constituted by 30th DCC requiring consideration consequent to decision of the 30th DCC.**

1. **Item No. 3 : Consideration of the proposal for curtailing the number of licences required fro stocking, distribution or sale of drugs.**

The Sub-Committee report proposed by Commission, FDA, Maharashtra, Director – Drugs Controller, West Bengal, Drugs Controller, Delhi and Drugs Controller, Karnataka, has been placed in Annexure B of the Action Taken Report.

The major features of the report is to do away with separate licences for drugs specified in Schedule C & C1 and other than those specified in Schedule C & C1. It is felt that the Form 19, 19A, 20, 20-A, 20-B and 20-BB would require minor amendment with corresponding changes in the Rules. Also Forms 21, 21A, 21B and 21BB would be deleted.

In absence of any comment from the members within the stipulated time period, the committee felt that the proposal may be taken up and the sub-committee report may be accepted for necessary amendments in the Drugs & Cosmetics Rules.

2. **Item No. 10 : Consideration of exemption from selling distribution licence for product 'Vaseline – White Petroleum Jelly IP'.**

Taken as fresh Supplementary Agaenda item No. 1.

3. **Item No. 11 : Consideration of inclusion of Buprenorphine in Schedule X in the Drugs & Cosmetics Rules.**

Experts differed in their opinion and there was no consensus with reference to extent of abuse of Buprenorphine in the country except from certain regional pocket, where abuse of the drug has been reported.

In view of the above, it is proposed that the extent of abuse should be studied in the Addiction Centres located in Govt. Hospitals by taking detailed history of the drug induced addiction coming to the centre for counseling and deriving longitudinal studies of Buprenorphine abused cases in such cross-section with reference to abuse due to other drugs, viz. Pentazocine, Diazepam, etc.

Members may give their opinion in this regard.

4. **Item No. 13 : Consideration of stocking of drugs labeled as Physician's samples in residential premises and unlinecsed premises.**

Members agreed to the sub-committee's report for necessary amendment in the Drugs & Cosmetics Rules.

5. **Item No. 14 : Consideration of publication of the names of the manufacturers of the not of standard quality drugs in the press and other actions to be taken.**

After discussion the Chairman is of the view that DDCI, West Zone will give a write-up on the matter.

6. **Item No. 17 : Consideration of powers to prosecute under DMR (OA) Act, 1954.**

The matter has been discussed at length. However, no conclusion has come out and the Chairman decided that a sub-committee to be constituted with the following members :

1. Drugs Controller, Kerala
2. Drugs Controller, Delhi
3. Drugs Controller, Orissa
4. Drugs Controller, Goa
5. Jt. Drugs Controller (AK)
6. DDCI, West Zone, Mumbai (Member-Secretary)

(Annexure III to be circulated to all members)

7. **Item No. 32 : Consideration of the question whether animal food preparations which are fortified with vitamins are to be drugs.**

The sub-committee of the 30th DCC could not meet and the members after discussion requested the Chairman to make a sub-committee to constitute with the following members :

1. Mr. Vishwanathan, Dept of Animal Husbandry & Diarying

2. Representative from Central Board of Customs
3. Representative from DGFT, Ministry of Commerce
4. Representative from Food Manufacturers' Association
5. Commissioner, FDA, Gujarat
6. Dr. Malik from IVRI
7. Dr. Janaki Reddy from Andhra Pradesh
8. Director, CIPL, Ghaziabad
9. DDCI, West Zone, Mumbai (Member Secretary)

The draft agend will be made by DDCI, West Zone, and circulate it to all the members. The meeting to be held in Mumbai.

Member-Secretary will inform the policy makers for amendment. The report will be submitted by six months.

8. **Item No. 38 : Consideration of imported raw materials of B.P. and USP standards in respect of Calcium Pentothenate.**

The Commissioner, FDA-Gujarat will look into the matter and give a write-up to the Drugs Controller General (India) within 3 months time.

9. **Item No. 42 : Consideration of policy to be framed in respect of testing samples drawn and sent to the Govt. Analysts with very short expiry remaining.**

Members agreed with the policy recommended by the Commissioner, FDA, Maharashtra.

10. **Item No. 46 : Consideration of the actions to be taken under the Drugs & Cosmetics Rules of the not of standard quality test report declared by an approved testing laboratory.**

Specific comments forwarded by the Director, CDL, Calcutta should be circulated to all the members for their comments on this matter. (It is already there as Annexure V)

11. **Item No. 47 : Consideration of the examination of the extent and conditions of exemption provided under point No. 10 of Schedule 'K' for milk preparations and cereal preparations, fortified with vitamins and minerals, to be used for drugs – Classification of products containing Protein hydrolysates, Vitamins and Minerals, etc.**

The Chairman, while highlighting the agenda item, brought out that there are some preparations containing protein hydrolysates, vitamins, minerals and herbs available in the form of liquids, capsules, powders, etc. having

no therapeutic claims and hence such products could not be classified as 'drugs' as per provisions of Drugs and Cosmetics Act, 1940.

On his request, Assistant Director General (PFA) clarified that as per draft guide lines for Vitamins and Mineral supplements brought out by Codex – a joint body of FAO / WHO, vide alinorm 95/26, Appendix VI read with the document CL 1997/11 – NFSDU dated ... July, 1997, Dietary supplement, containing Vitamins and Minerals, should be regarded as 'Food' within the Codex system.

Whether or not, they should be regarded as 'Drugs' is left to the discretion of Naional Authorities.

ADG(PFA) further informed that though these products were earlier covered under 'Drugs' but on the request of Drugs Controller General, the issue was debated by the Central Committee for Food Standards (CCFS) – statutory advisory Committee under the provision of PFA Act.

The CCFS recommended that such Dietary supplement, without any Medicinal claim, be treated as 'Food' and could be marketed only under a licence under PFA Rules, 1955, which is given by the State Govts / Local Bodies.

The CCFS has constituted an Expert Group under the Chairmanship of Director, CFTRI, Mysore, comprising other experts, including Joint Drugs Controller of Directorate General of Heatlh Services, to decide the parameters for quality control of such products.

The CFTRI, Mysore, has already analysed large number of samples and is expected to submit its report shortly, which will be made available to the Office of the Drugs Controller General India so that the finding could be shared with the State Drugs Controllers.

The Drugs Consultative Committee observed that there are certain preparations, which are not mentioning any therapeutic claim on the label, but depicting some pictures / photographs on the labels indirectly implying health benefits.

There are also certain preparations which are solely based on 'herbs' which could be classified as 'Ayurvedic Drugs'. A list of such products would be made available by the State Drugs Controllers / Officers of Drugs Control Division of Directorate General of Health Services for examination.

For this a sub-committee has been constituted with the following members :

1. ADG (PFA) – Chairman
2. Drugs Controller, West Bengal
3. Drugs Controller, Jammu & Kashmir
4. Drugs Controller, Karnataka
5. Drugs Controller, Tripura
6. Jt. Commissioner, FDA-Maharashtra
7. ADC (Mr SP Das) – Member-Secretary

On a query raised by ADG (PFA), it was clarified that as per practice prevailing so far, the products containing Vitamins, Minerals, etc. are generally imported on the basis of a licence issued under Form 10 of Drugs & Cosmetics Rules, 1940. However, in case of doubt as to whether the product should be classified as a food article, some time reference is made to the PFA Division.

The DCC agreed with the suggestion made by ADG (PFA) that if an article containing Vitaminis, Minerals imported into the country is not considered to be a Drug, the Officers of Drugs Control posted at the port may inform the Custom, who are aware of the procedure of clearance of an imported article of food under Section 6 (2) of PFA Act, 1954.

In general, Custom Collectors seek the assistance of Port Health Officers under Section 151 (d) of Customs Act, who in turn get the samples analysed by Central Food Laboratories (situated at Calcutta, Ghaziabad, Mysore and Pune) depending on jurisdiction.

ADG (PFA) also clarified that products like Milk Powder, Cereal preparations fortified with Vitamins and Minerals are covered under the provisions of Prevention of Food Adulteration Act, 1954.

In case of Baby Food, the PFA Rules define Infant Milk Substitute as well as Infant Food (first solid food to be given to the Infant from 4 months of age). Standards for Infant Milk Substitute, Infant formula, Low Birth Weight Infant Milk Substitute, Milk Cereal based weaning Food and Processed cereal based weaning Food have been laid down and these are to be compulsorily certified by Bureau of Indian Standard. Other types of special Infant Milk Substitutes, like Lactose – free Infant Milk Substitute meant for Lactose intolerant infants or low fat Infant formula to be given to Infant under specific conditions are required to be approved by the Central Government under the provisions of Prevention of Food Adulteration Rules, 1955.

12. **Item No. 64 : Consideration of maintaining control reference samples by the Cosmetics manufacturers.**

The Chairman should again approach BIS for involving their laboratories.

As regards reference samples of Cosmetics, if agreed, we will write administrative letters to all the State Drugs Controllers.

BIS has their own cosmetic testing laboratories. We may take up this matter with them and sensitise them to test for cosmetics and we may give them legal status.

13. **Item No. 65 : Consideration of the issuance of conclusive test reports by PLIM Laboratory, Ghaziabad.**

The Chairman has decided that the matter should be taken with the Secretary, ISM, as the Director of PLIM has shown reservations for sending the samples rested with PLIM.

C. CENTRAL AGENDA

Item No. 1 : Consideration of the proposal to amend rule 64 so as to prohibit or restrict excessive concentration of Chemists' Shops at a particular location.

After long discussion, the members decided that a sub-committee should be framed to settle the issue with the following members :

1. Commissioner, FDA, Gujarat – Chairman
2. Drugs Controller, Kerala
3. Drugs Controller, Punjab
4. Drugs Controller, Tripura
5. Drugs Controller, Orissa
6. Drugs Controller, Silvassa
7. Drugs Controller, Jammu & Kashmir
8. Jt. Drugs Controller (Dr. S R Gupta) – Member-Secretary

All the members will send their views to the Member-Secretary and the committee will give its report by six months.

Item No. 2 : Proper amendment under rule 121 of Drugs & Cosmetics Act related to test for freedom from abnormal toxicity.

After discussion, the members agreed to amend the rule.

Item No. 3 : Proposal regarding the monitoring of banned drugs in the country.

After discussion, the Chairman opined that each State should forward the data, quarterly, in respect of banned drugs to DCGI.

Item No. 4 : Proposal regarding monitoring on quality / efficacy of the Biological products (Human / Veterinary) including veterinary drugs.

It has been decided to identify one Inspector or ADC responsible for Veterinary drugs and send the names to DCGI, which will be sent to IVRI.

So far veterinary drugs are concerned, members agreed that the proposal made under the agenda will be followed as decided in the meeting.

So far veterinary vaccines are concerned, members decided to take opinion from the Director, IVRI regarding the procedural aspects for sending the samples drawn by the Drugs Inspectors.

Item No. 5 : Proposal regarding incorporation of 'best use before' on marking clause of cosmetic product packs.

Mr. Satish Chandra, Director, BIS stated that while they are formulating the National Standards, they formulated through a Committee, which consists of the representatives from large Manufacturers, Consumer Bodies, Laboratories undertaking research in this area.

It was decided that the terms "Best use before ....." should be labeled and it should be mandatory for all the cosmetics.

The matter is under consideration by the BIS whether all the ingredients to be given or only the critical ingredients to be given on the label. The decision will be intimated to all the members as soon as the same is received from BIS.

Item No. 6 : Consideration of proposal to revise specifications of condoms under Scheduel 'R' as per the recommendations of WHO Guidelines issued in 1995.

After discussion, the members agreed to amend the rule.

Item No. 7 : Proposal regarding suitable amendment under Entry No.27 of the banned drugs notification in respect of fixed dose combinations of Oestrogens and progestin.

The members after discussion requested the Chairman to address the matter to Consumers' Organisations, particularly Women Organisations for their opinion.

Item No. 8 : Consideration of the proposal regarding Bilingual 'Insert Slip' in Schedule 'H' Drugs for making suitable amendment under the labeling provision of Drugs & Cosmetics Act and Rules.

After a lengthy discussion, the Chairman requested to all the members to take up the matter with their respective State Govts., under intimation to this Directorate.

Item No. 9 : Proposal regarding involvement of NGOs in various Drugs Advisory Committees at State / Central level.

After discussion with the members, the Chairman suggested that all the members should call NGOs in various Drugs Advisory Committees at States and to take their suggestions / views as far as practicable.

Item No. 10 : Consideration of the proposal to amend Rules 74(J), 78(i) and 65(17) (b) of the Drugs and Cosmetics Rules, 1945 for expeditious recall of impunged samples of drugs by the manufacturer and sales outlets.

The Drugs Controller, Karnataka has suggested that the words "Drug Inspectors" should be added after the word "manufacturer" in the sixth line in Point No.Rule65 (17) (b).

The format of the certificate to recall the drugs will be sent by the FDA, Maharashtra to DCGI for necessary action in this matter.

Item No. 11 : Proposal for consideration of fees for WHO Certification Scheme on quality of Pharmaceutical products moving in international commerce.

There will be a meeting on this issue and the WHO Certification Scheme will be taken up by DCGI. Members will be intimated separately.

Item No. 12 : Consideration of the proposal to amend Drugs and Cosmetics Rules, 1945 to grant exemption under certain specified conditions to peripheral institutions run by Government which are collection for transfusion of whole human blood under emergency situations.

DGMS (army) has requested for exemption from having licence for Blood Bank / Blood transfusion in remote border areas. In such areas, having a regular licensed / authorized Blood Bank, is not possible. The contention was that the blood transfusion does take place during conflicts, insurgency, terrorist operations, etc. where immediate blood transfusion is required. This type of transfusion is done from jawan to jawan basis then and there under the supervision of their own doctors after carrying out

matching and screening of the blood. This is done rarely under emergent circumstances.

The Chairman, Drugs Consultative Committee (DCC) desired to know the views of members and also experts present like Dr. Sardana of NACO and Dr. Vijay Lakshmi Ray, Deputy Director, NIB New Delhi.

During deliberations, a point was raised that if at all an exemption is granted to Army, the PHCs / CHCs in rural areas where the Mother and Child Care Programme is run, will also come forward for exemption whose Blood Banks / Blood Transfusion Centres have not been recognized so far in many areas due to non-fulfillment of requirements of licensing procedures.

Meanwhile, it was brought to the notice of DCC by DC, Goa, that there are certain protected areas in Goa, where Army runs their own Blood Banks without licence or any authorization. No one is permitted to visit this prohibited area for security reasons.

To this, the Chairman advised that DC, Goa should write a letter to Army authorities enclosing a copy of Supreme Court's judgement on the subject and request them to obtain licence for running such Blood Banks.

The members opined that while they have all the sympathy for Army, they would like to have more detailed information about the frequency of emergent situations, storage, matching, transfusion and transportation of blood, etc. to understand the magnitude of the problem faced by Army in Border areas.

Finally, a consensus decision was taken to address a letter to DGMS (Army) requesting them to furnish more details which will be circulated among the members to take a final decision in the matter keeping the Supreme Court directive in mind.

Then many of the members, specially from Assam, Arunachal Pradesh, Mizoram and other North –Eastern States requested for examination under certain specific conditions to peripheral institutions run by Government which are collecting for transfusion the whole human blood under emergency situations.

After deliberation, from each respective State, the Chairman concluded that a Sub-Committee should be formed with the following members to examine the whole issue and the recommendations of the sub-committee will be a guideline for taking further necessary action in future. Accordingly, the sub-committee is formed with the following members :

1.	Drugs Controller, Kerala (Mr. S. S. Venkatakrishnan)	Chairman
2.	Drugs Controller, Punjab (Dr. Harpal Singh)	Member
3.	Drugs Controller-cum- Inspector General (AP) (Mr. K Jaganath Rao)	Member
4.	Commissioner, FDA, Gujarat (Mr. S P Adeshara)	Member
5.	Jt. Commissioner, FDA, Maharashtra (Mr. V M Bobade)	Member
6.	Asstt. Drugs Controller, Assam (Mr. s Bhattacharya)	Member
7.	Asstt. Drugs Controller, DGHS, Nirman Bhawan (Mr. R Narayana Swamy)	Member-Secretary

Item No. 13 : Consideration of the proposal to insert the rule 148 provisions relating to safety testing of cosmetics with minimal use of animals.

After discussion, members felt that instead of the words "should display" in the line No. 8 of the 4th paragraph, it should be read as "may display" and necessary amendment should be done.

Item No. 14 : Matters concerning grant or renewal of licences to manufacture Large Volume Parenterals (LVPs).

After discussion, the members felt that so far the Part A is concerned, necessary legal opinion has to be sought from the Dept of Legal Affairs. FDA, Gujarat and Maharashtra will forward the information about the Loan Licence holders.

Regarding Part B, the Chairman stated that, except export, more than one brand name may not be allowed for a single product / formulation for the same manufacture.

Item No. 15 : Consideration of the proposal to omit Amaranth, Green –S, Fast Red E from specified colours listed under rule 127 of the Drugs & Cosmetics Rules, 1945.

After discussion, the members agreed to amend the rule.

Item No. 16 : Consideration of the proposal to insert under Schedule H Steroidal Ophthalmic preparations.

After discussion, the members agreed that Steroidal Ophthalmic preparations should be brought under Scheduel H list of the Drugs and Cosmetic Rules.

Item No. 17 : Proposal to bring out Third volume of the minutes of DCCs.

It will be taken care of by the office of CDSCO. However, necessary inputs, as and when required, will be requested from the concerned members of DCC.

Item No. 18 : Grant of licences on Form 20B and 21B for wholesale of drugs in accordance with provisions of Rule 64 of the Drugs & Cosmetics Rules, 1945 – Clarification concerning qualification and experience of competent persons.

After discussion, the members felt that the matter can be settled by providing the following amendment in the Rule :

In the Proviso No. 3 under Rule 64, in the second line the word "with" should be read as "and".

Item No. 19 : Consideration of the proposal to amend relevant rules of the Drugs and Cosmetics Rules, 1945 with regard to upward revision of fee structure prescribed for grant / renewal of sales and manufacturing licences including Homoeopathic, Ayurvedic, Cosmetics and testing of drugs and enhancement of the period of sale licences.

While discussing the fees structure for sale / manufacturing licences, the members had varying opinion. Though there was consensus among the members about the uniform upward revision of fee, opinion varied about the period and renewal of manufacturing and sale licence.

In order to have uniformity, the Chairman constituted a sub-committee as follows :

1.	Commissioner, FDA, Maharashtra	Chairman
2.	Commissioner, FDCA, Gujarat	Member
3.	Drugs Controller, Delhi	Member

4.	Drugs Controller, Orissa	Member
5.	Drugs Controller, Goa	Member-Secretary

The Chairman intimated that the recommendations of the sub-committee will be circulated among all the State Drugs Licensing Authorities as soon as the Committee submits the report.

Further, the Chairman decided to place the comments and recommendations of DCC in the next meeting of the Drugs Technical Advisory Board (DTAB) for approval and also to utilize the enhanced fee earned for improvement of working of the Departments in all the States.

Item No. 20 : Consideration of proposal to allow the transition period for another 3 to 6 months in certain cases for compliance to Indian Pharmacopoeia requirements.

Dr. P. R. Pabrai, Member, Indian Pharmacopoeia Committee, has mentioned that Drugs Industries have made representation about certain tests / specifications given in I.P., 1996. He was emphasizing on the period of time given to manufacturers for carrying out changes in the package inserts, promotional literature, labeling, etc. for the mistakes committed due to printing errors and issuance of rectification orders. He reiterated that Licensing Authorities should take pragmatic view in granting time to manufacturers for updating the labels, etc., according to the amended I.P.

Members of DCC agreed for giving adequate time to manufacturers. As the powers for rectification of errors rests with the I.P. Commission, the Chairman assured that a letter will be sent to I.P. Commission in this regard and the reply will be circulated among the State Drugs Controllers.

Item No. 21 : Consideration of the proposal to permit the marketing of Combipack in the country.

After prolonged discussion on combipacks, the DCC made the following recommendations with regard to labeling of such packs :

1. The label should bear the licence number in Form 25 and Form 28.

2. Generic name and the strength of each individual drug should be mentioned on the label.

3. Date of Manufacture (DOM) and Date of Expiry (DOE) should be mentioned. The DOM will be the date of packing of the pack and DOE will remain the same as for the lowest expiry drug.

4. The label should discuss the composition of each drug.

5. Batch numbers of each drug should be mentioned.

6. All combipacks should be approved only after having a detailed examination by the Drugs Controller General (India).

7. In order to avoid complications, all the individual drugs should be manufactured in one place and should be packed in the combipack in the same place.

Item No. 22 : Consideration of the proposal to dispatch "Copy of the test report " meant for Drugs Controller General (India) being forwarded by the Government testing to Zonal Officers.

After prolong deliberations regarding submission of test reports, an unanimous decision was taken that one extra copy of the test report of the samples, whether standard quality or sub-standard quality, be sent to the Zonal Office which will in-turn inform DCG(I). The State Drugs Controller should also be sent a copy of the test report in the State in which the zonal office is located. As far as CDL, Calcutta is concerned, it will directly send the report to DCG(I).

Item No. 23 : Consideraton of the proposal to amend Schedule F-II in respect of standards for surgical dressings, viz. Gauze and Bandages.

While discussing about laying down of standards for surgical dressings, the Chairman took the decision as the standards are laid down by the Bureau of Indian Standards (BIS), the comments of BIS has to be obtained in the first instance before taking any final decision in the matter.

Item No. 24 : Proposal regarding inclusion of GOOD CLINICAL TRIAL REGULATIONS IN INDIA under "Schedule Y" of Drugs and Cosmetics Act and Rules thereunder.

While discussing about the inclusion of "Good Clinical Trial Regulations in India" under "Schedule Y" of the Drugs and Cosmetics Act, the Chairman emphasized the need and importance of Good Clinical Practices inter-alia clinical trials of drugs in the country. A decision was taken to circulate the draft guidelines framed, covering Phase I to Phase III studies, among the State Drugs Controllers, to invite their comments before it is incorporated under "Schedule Y". Fro this purpose, the Chairman has constituted a sub-committee as follows :

1. Mr. Ashwini Kumar, DDC(I) Chairman

	DGHS, Nirman Bhawan, New Delhi	
2.	Drugs Controller, Punjab	Member
3.	Commissioner, FDA, Maharashtra	Member
4.	Drugs Controller, West Bengal	Member
5.	Drugs Controller, Karnataka	Member
6.	Shri R. Sengupta, Consultant	Member
7.	Shri A. B. Ramteke, DDC(I) DGHS, Nirman Bhawan, New Delhi	Member-Secretary

The entire exercise has to be completed within three months.

Item No. 25 : A proposal regarding rationalization of Fixed Dose Combinations (FDCs) moving in the market with various proportion in respect of following (a) Dextropropoxyphene with Paracetamol, (b) Ibuprofen with Paracetamol and (c) Diclofenac Sodium with Paracetamol.

Discussing the availability of some of the Fixed Dose Combinations in the country, in different strengths, Chairman desired to streamline and bring uniformity in FDCs. Some members stated that some of the FDCs are already in the latest I.P. However, Chairman was more particular in uniform implementation and took a decision to address all State Drugs Controllers by sending a letter to them inviting their comments in this regard.

The Chairman requested Mr. Ashwini Kumar, DDCI, HQ, should take initiative and finalise the matter within the shortest possible time.

Item No. 26 : Proposal regarding uniform pack size of Drugs / Formulations moving in the market in conformity with the Rule 105 of Drugs & Cosmetics Act and Rules.

Mr. Shantanu Consul, Jt. Secretary, Ministry of Chemicals & Fertilisers has stated that in the entire business of Price Control, situation is entirely complicated because large number of producers and bulk drugs are involved. To bring them under price control and to ensure that the prices implemented, take action against the companies which are not following the norms of pirce control, which is a cumbersome business. He also stated that they are totally dependent upon the State Drugs Controllers. The Dept of Chemical has no representatives in the States. The DPCO was brought out under the Essential Commodities Act and it

has a social purpose to perform. The drug companies are not happy with the price control. Every company tries to escape the drugs price control in one form or the other. 50% of the formulations are under price control.

He identified few points as follows :

1. The National Pharmaceutical Pricing Authority would start functioning very soon. This will do price fixation, piree follow-up and monitor Drug Price Control Order. For this they need co-operation from the States.

2. Under the World Bank Scheme, National Institute of Pharmaceutical Education and Research (NIPER) will be helping the staff of the Drugs Controllers in training, exposure, effective screening, quality control. They will also be conducting the training courses for new recruitees other than exsiting staff.

3. The Ministry will send a format to all the State Drugs Controllers. All the State Drugs Controllers should bring out a list of all the manufacturers with their addresses and products being manufactured by them, from time to time.

   In the case of companies manufacturing bulk drugs, names, addresses & installed capacities along with names of the bulk drugs, can be given and for small units manufacturing formulations, which run in large number, only the names & addresses can be given.

   A time span of 30 days was given.

4. As some of the manufacturers are denying that some formulations are not being manufactured for which they got permission, to avoid price fixation, the State Drugs Controllers have to confirm this.

5. The pack size & strengths are being changed according to whims & fancies of the producers. For keeping uniformity, all State Drugs Controllers are requested to standardize the pack size. Need for different pack size should be based on rationality.

   Besides packs sizes, change in the ingredients & brand names is also there. Composition of the drugs are being changed with the same brand names.

   Different brand names being issued for one product to the same company.

Regarding the delegation of powers, the matter is under consideration at the Law Ministry.

It was decided that the pack size should be made mandatory in the manufacturing licence.

Item No. 27 : Consideration of proposal to request the State Licensing Authorities to follow-up the payments of testing fees to the Central Drugs Laboratories.

It was brought to the notice of the Committee that the testing fees of samples of drugs forwarded by State Drugs Inspectors to CDL, Calcutta, CIPL, Ghaziabad and CRI, Kasauli are not paid in time and the arrears are mounting.

The Chairman directed the offending States to do the needful in this regard to which they had committed to clear the arrears immediately.

The Chairman further desired that imported samples sent for testing to National Laboratories should also be charged by the laboratories from the Importers / Manufacturers.

Item No. 28 : Consideration of proposal to write complete postal address of the Centre / State Drugs Inspectors in Form 18 while forwarding the samples to the Central Drugs Laboratory, Calcutta.

In order to mitigate the difficulties experienced by the Director, Central Drugs Laboratory, Calcutta, in dispatching test reports, to the correct addressees, the Chairman advised all the State Drugs Controllers to direct their enforcement staff to give full address including the Pin Code while sending samples for testing to CDL, Calcutta.

Item No. 29 : Consideration of the proposal to provide uniform action under Drugs Price Control Order for charging the price exceeding the price stated on the label of the container.

Please read with the minute of Item No.26 above.

ANDHRA PRADESH

Item No. 30 : Proposal for the amendment to Rule 85 of Drugs and Cosmetics Rules enabling the licensing authority to take action also on the technical staff who are directly involved in the manufacturing of any drug declared as not standard quality.

After prolonged discussion, the members could not come to a conclusive decision and the Chairman suggested that *Status Quo* should be maintained in the matter.

DELHI

Item No. 31 : Consideration of inclusion of all "Schedule G" drugs in "Schedule H" and the resultant omission of "Schedule G" from the Rules.

While debating about inclusion of all Schedule G drugs under Schedule H, members opined that there is scope of shortening the list of drugs under Schedule G not by shifting all the drugs to Schedule H, but a selected few.

In order to achieve the goal, the Chairman constituted a sub-committee with the following members:

1.	Commissioner, FDCA, Gujarat	Chairman
2.	Drug Controller, Punjab	Member
3.	Drugs Controller, Delhi	Member
4.	Asstt. Drugs Controller DCCI, Nirman Bhawan, New Delhi (Mr. B R Wadhawan)	Member-Secretary

The Chairman also desired that some clinical experts may be involved in the task and the Member-Secretary should write letter to all the State Drugs Controller in this regard.

DADRA & NAGAR HAVELI, SILVASSA

Item No. 32 : Proposal for inclusion of a Rule regarding prohibition against altering inscription of containers, labels or wrappers of cosmetics.

The proposal was discussed in detail. The Chairman desired that all State Drugs Controllers should send their suggestions on Hair Oil, Shampoo, Tooth Paste, etc. and Shri B R Wadhawan, ADC(I) will co-ordinate and do the needful in amending the Rules for Cosmetics.

GOA

Item No. 33 : Consideration of the question to manufacture Diagnostic reagents / kits under manufacturing licence and their labeling.

While debating about the import of diagnostic kits and re-labelling it, the DCC was informed that the import of diagnostic kits are regulated by issuing Form 10 licence. NICD and NIV carry out sensivity and specificity tests for these kits.

Dr. Vijay Lakshmi Ray, Deputy Director, NIB opined that NIB cannot control all the activities and stressed on the need of formation of a committee. Presently, NIB is looking after the testing of immuno-diagnostic kits particularly for Blood Banks. The tests are carried out on priority basis for HIV and Hepatitis B. She desired that the committee should inspect manufacturing unit along with the representative from CDSCO to ascertain whether the units have all the facilities. To have result oriented exercise each application has to be screened by the Committee. She desired that the CDSCO should work together in close co-ordination. She also felt the need of a certificate from the country from where the kits are being imported or from any international laboratory. This should be checked while reviewing the applications for grant of licence.

The Chairman requested to all the members to note the proceedings of the discussion and if they feel, they may send any further opinion / comments in the matter.

Item No. 34 : Consideration of the proposal for reducing the period of training programme of 2 years which is provided under Rule 44 (a) and 44 (b) of the Drugs and Cosmetics Rules, 1945.

After discussion, the Chairman desired that all the State Drugs Controllers should prepare a write-up on reputed laboratories and to send to DCG(I) for taking necessary action.

Item No. 35 : Proposal related to the Constitution of the firms.

The members did not agree with the proposal and finally the proposal was withdrawn.

Item No. 36 : Proposal to amend Item No. 56 of banned drugs Notification vide GSR 633(E) dated 13.9.95.

After deliberation, the Chairman desired that the Advisor ISM should be asked to include the hard gelatin capsules in their Schedule as many Ayurvedic medicine now being filled and sold in capsule form.

The Chairman requested Mr. Ashwini Kumar, DDC(I) to take up the matter with the Dept. of ISM in this regard.

KARNATAKA

Item No. 37 : Proposal for correction on Section 27-A(i) in relation to penalty for manufacture, sales, etc. of cosmetics in contravention of Chapter IV of the Act.

All the members unanimously agreed to the proposal. The proposal is also intended to be clubbed along with matter concerning NDA Bill as and when the same is carried out under Drugs and Cosmetics Act amendment.

Item No. 38 : Proposal to assign date of commencement of manufacture and date of completion of manufacture in Batch Manufacturing Record under "Schedule U" of the Drugs and Cosmetics Rules.

All the members unanimously agreed for making suitable amendments under Schedule U of the Drugs and Cosmetics Rules.

Item No. 39 : Proposal regarding the status of condoms and surgical sutures added with colours.

The matter has been discussed at length with the representatives of BIS.

It has been decided that the Drugs Controller, Karnataka, will give some specific colours, other than the colours already mentioned in the Rule 127(i), which can be used in the manufacturing of Condoms.

The same will be forwarded to BIS for their opinion and further necessary action.

Item No. 40 : Proposal for inclusion of certain workings in entry 52 of banned drug under Notification No. GSR 57 (E) dated 7.2.95.

All the members unanimously agreed for necessary change in the entry No.52 of the Banned Drug Notification GSR 57 (E) dated 7.2.95.

Item No. 41 : Proposal for modification of the content of the prescription under Rule 65 (10).

While discussing modification of the content of prescription, the Chairman suggested that the matter may please be forwarded to Medical Council of India for their initial opinion for taking further action in this regard.

KERALA

Item No. 42 : Proposal for reviewing the licence procedure of Large Volume Parenterals and Blood Banks.

The proposal was discussed in detail. Except DC, Kerala and DC, Maharashtra, all other members agreed, but opined that delay at different levels should be avoided. In view of this, the Chairman decided to maintain the *Status Quo*.

Item No. 43 : Proposal to control of sale of psychotropic substances.

After long discussions on the matter in respect of Drugs & Cosmetics Act as well as with the NDPS Act, the members decided that NDPS Act may take its own course of action and it was felt that no discussion was to be needed further on NDPS Act as the same has already been well illustrated.

Finally with the concurrence of all the members and with the permission of the Chair, the proposal was withdrawn.

MAHARASHTRA

Item No. 44 : Proposal to include provisions to direct withdrawal of stock of drugs in case of loan licence.

The matter was discussed at length. On the basis of the recommendations from the members, the Chairman desired that the Ministry of Law should be consulted in the matter. Subsequently, the FDA Maharashtra had been requested to take opinion from the Legal Dept. of their State and forward the same to DCG(I) for taking necessary action.

Item No. 45 : Proposal to maintain reference samples from each batch of drug by manufacturer in a quantity which is at least double the quantity of the drug required for complete testing.

All the members had pointed out that the said provisions already exists in the Drugs & Cosmetics Rules and there was no need for further discussions.

MIZORAM

Item No. 46 : Proposal to appoint Central Drugs Laboratory as Government Analyst for the State of Mizoram.

The Chairman advised the Drugs Controller, Mizoram, to take up the matter with the Director, Central Drugs Laboratory, Calcutta, through the State Govt. of Mizoram. He also intimated that the Govt. of Mizoram has to notify the CDL, Calcutta as their Govt. Analyst through Gazette Notification.

TAMIL NADU

Item No. 47 : Proposal for amendment of Section 23 (4) (iii) of the Drugs and Cosmetics Act, 1940 for hand over the 3rd portion of the sealed sample drawn by the Drug Inspectors to the concerned manufacturers of drugs.

All the members agreed for necessary amendments.

The proposal also intended to be clubbed along with the matter concerning NDA Bill as and when the same is carried out under Drugs and Cosmetics Act amendment.

Item No. 48 : Proposal for making provision for prior sanction for launching prosecution under DPCO, 1995.

After discussion, the Chairman felt that the matter should be referred to the Dept. of Chemicals & Petrochemicals under the Ministry of Chemicals & Fertilizers to include necessary provision for launching prosecution under DPCO, 1995.

Accordingly, the Chairman advised the Drugs Controller, Tamil Nadu to take up the matter with the Dept. of Chemicals & Petrochemicals under intimation to this Directorate.

OPPI

Item No. 49 : Consideration of proposal to review the classification of category A and B defects withdrawal of not of standard quality Drugs form the market.

Please read with the minute of Item No. 10 above.

D. SUPPLEMENTARY AGENDA

Item No. 1 : Reconsideration of exemption from the provisions of sale licence from selling / distribution of White Petroleum Jelly (Vaseline) and inclusion thereof under Schedule K of the Drugs & Cosmetics Rules, 1945.

The Chairman requested the members to refer to Item No. 10 of the 'Statement of Action taken of the 30th DCC held on September 6-7, 1995, at New Delhi' whereunder it was proposed to give exemption to White Petroleum Jelly I.P. from the conditions of sale licence under Schedule K of the Rules.

After discussion, the members unanimously decided that the said item could be given exemption under Schedule K for the reasons that it is being used for a variety of minor skin problems (like cuts, bruises, chapped lips, cracked heels, rashes, burns, etc.) besides being non-irritating, non-toxic and does not need specialized storage conditions.

However, it is proposed that instead of putting under entry 26 of Schedule K relating to "medicated dressings and bandages for first aid", it could be placed at any other appropriate entry of Schedule K as "non-perfumed White Petroleum Jelly".

Item No. 2 : Reconsideration of the constitution of Expert Standing Committee for in-depth examination for amending provisions of Drugs & Cosmetics Act, 1940, and Rules thereunder.

The Chairman invited reference to Item NO. 14 of 26th DCC meeting held at New Delhi on September 14-15, 1989, whereunder an Expert Standing Committee was constituted under the Chairmanship of Commissioner, FDA, Maharashtra, having members from Tamil Nadu, West Bengal, Kerala, Delhi, Karnataka and a member from CDSCO to undertake an in-depth examination of various suggestions made by the State Drugs Controllers requiring amendments of the provisions of Drugs and Cosmetics Act, 1940 and Rules thereunder.

The Chairman proposed to the members to reconsider the constitution of the said Standing Committee in the light of some members, who were actively participating in the said Committee to have since retired or got transferred.

The members decided that Shri S P Adeshara, Commissioner, FDA, Gujarat, shall now be the Chairman of the said Committee and Shri B R Wadhawan, Asstt. Drugs Controller (I), DGHS, New Delhi, shall be the Member-Convenor of the said Standing Committee. The Chairman may choose other members as per the requirements of the items to be deliberated.

The matters raised by the invited representatives from OPPI, IDMA, Chemists & Druggists' Association and All India Small Scale Manufacturing Association have been clarified by the respective members of the DCC to their satisfaction on the second day of the meeting.

The meeting ended with a Vote of Thanks to the Chair.

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Annexure – I
(Item no. 2 of the 31st meeting)

Statement showing the action taken on the decisions taken at the 30th Meeting of the Drugs Consultative Committee held in New Delhi on the 6th & 7th September 1995.

NO.	SUBJECT DISCUSSED	DECISION TAKEN	ACTION TAKEN
(1)	(2)	(3)	(4)
1.	Consideration of the proposal concerning curtailing number of licences for drugs specified under Schedule C and C(1) and other than Schedule C and C(1) – Report of Sub-Committee under Item No.3 of 28th D.C.C.	The Chairman requested to all the members to send their comments within three months.	No comments have been received from the member so far.
2.	Consideration of the report of the question as to whether drugs can be permitted to be repacked in the pack size other than those specified by the Drugs Controller (India) vide circular No.19013/4/80-D dated 12.3.1982 – Item No. 30 of 29th D.C.C.	The Chairman concluded that the items viz. Homatropine Hydrobromide I.P. Pilocarpine Nitrate I.P., Sulphacetamide Sodium I.P. have ophthalmic use and the same should be deleted from the repacking list. The members have been requested to give their comments within 3 month's time.	Further, comment received from FDA, Maharashtra to delete Atropin Sulphate, Benzyl Alcohol, Chlorobutol as these items are used for insectable grade only and also Bismuth sub carbonate, Sucrose as these items are not commenly used for dispensing.
3.	Consideration of the question to bring Ayurvedic, Unani and	It was concluded that the matter may be kept pending till final recommendations	The matter is still under examination by ASU. DCC/ASU DTAB.

	Siddha drugs under the purview of the sale licence – Item No. 45 of 29th D.C.C.	come from the Ayurvedic DTAB.	
4.	Consideration of exemption from selling / distribution licences for product Vaseline white petroleum jelly I.P.	Decision taken that Vaseline (where petroleum Jelly I.P.) to be exempted under should be Schedule 'K' of the Drugs & Cosmetics Rules under point no. 26.	Agenda is to be reported before the next DCC as same more discussion is to made on the issue.
5.	Consideration of inclusion of Buprenorphine in Schedule 'X' in the Drugs and Cosmetics Rules.	It was informed that expert opinion is being generated by the Dte. Accordingly, the matter may be taken up at next D.C.C.	
6.	Consideration of coating of a combination tablet formulation where a single ingredient present required to be coated.	After discussion, the Chairman requested the Drugs Controller, Delhi Administration to give a write-up in the matter.	The Drugs Controller (Delhi Admn.) forwarded a write up emphasizing that in case of double and multi conponant formulation, where one ingredient required coating of any kind and the other does not require any coating, the overall tablet formulation should be coated as the physico chemical aspects of the ingredient requiring coating are very much present in the multicomponent formulation also. However, exception of such ideas are also in the market such as Ibuprofen coated tablets and uncoated Ibuprofen and Paracetamol Tablet. Hence to decide the issue trial lots of the multicomponent formulations should be prepared and should be studied in both the uncoated and coated forms. Further

			the matter may be decided on the merit of individual cases.
7.	Consideration of stocking of drugs labeled as Physician's Samples in residential premises and unlicensed premises.	The DCC decided the matter should be examined by the subcommittee.	Report submitted by subcommittee for consideration. Sec. 13 and 27 may be amended by adding the words "for distribution" at appropriate places.
8.	Consideration of publication of the names of the manufacturers of not of standard quality drugs in the press and other actions to be taken.	The Commissioner, FDA Maharashtra stated that a complete report on the subject is expected by them by the end of September 1995 in the matter. The Chairman felt that the issue may be studied after receipt of the said report.	Report submitted by the Commissioner FDA, Maharashtra. Wherein suggested guideline in the matter has been placed for discussion in the next DCC.
9.	Consideration of powers to prosecute under DMR (OA) Act 1954.	The DMR (OA) Act is now under examination by a Sub-Committee.	As addressed by the Chairman, the members were required to furnish information to propose any further modifications required under DMR (OA) Act for the amendments could be placed before the DTAB or sent to the Ministry for their further appropriate action.
10.	Consideration of the proposals for including B.P. VET –1993 under Rule 124 A of the Drugs and Cosmetics Rules, in place of B.VET. CODEX.	Members agreed with the proposal.	The proposal has been sent to Ministry of Health to consider for publication as Draft Notification before finalization of the same.

11.	Consideraton of the proposal to provide administrative action under Drugs (Price Control) order for charging the price exceeding the price stated on the label of the containers.	The DCC decided, the matter should be examined by the subcommittee.	The subcommittee could not meet and follow up the issue. The matter may be taken up in next DCC.
12.	Consideration of the need to make suitable provisions for prohibition of Ayurvedic and Homoeopathic drugs purporting or claiming to cure certain diseases specified in Schedule J of drugs rules.	It was decided that the matter could be brought to the notice of Ayurvedic DTAB and Homoeopathic Advisor before taking any action in this matter.	Dept. of ISM & H is actively pursuing the matter in ASU DCC/ ASU DTAB.
13.	Consideration of the question whether animal feed preparations which are fortified with vitamins are to be drugs.	The DCC decided the matter should be examined by the subcommittee.	The subcommittee could not meet and follow up the issue. The matter may be taken up in next DCC.
14.	Consideration of the proposal to provide a rule prohibiting the altering inscriptions on the containers, labels or wrappers of the Ayurvedic and Homoeopathic preparations.	It was decided that the matter should be brought to the notice of Ayurvedic DTAB and Homoeopathic Advisor before taking any action in the matter.	The matter is still under examination by ASU DCC/ ASU DTAB.
15.	Consideration of the proposal to amend Rule 46 of the Drugs	It was decided that the Drugs Controller, Goa should send the judgement of the	Judgement of the case is not received. The matter is being persued with DC (Goa).

	and Cosmetics Rules for incorporating words "or an officer authorized by him" after the words, "Government Analyst".	case for examination.	
16.	Consideration of imported raw materials of B.P. and USP standards.	It was decided that the Director, CIPL will look into the matter and examine the case.	The Director, CIPL, is being followed up the matter with USP convention. Final action taken will be brought to be notice of the members as soon as the same is received.
17.	Consideration of the action to be taken by the Govt. Analyst when transfusion fluid samples are found with visible fungal growth in containers.	It was decided that the Director, CIPL will look into the matter and examine the case.	Comment received that if fungus is observed in a sample it should first be checked for any tampering, cracks or leakages etc. and if found intact then only presence of fungus should be reported. Test for sterility in case of samples containing fungus should not be carried out.
18.	Consideration of batch size for test or sterility by the Govt. Analysts to test the samples drawn by the Drugs Inspectors.	It was decided that the Director, CIPL will look into the matter and examine the case.	Comment received that Govt. analysts will report the standard of sample he/she receives not the batch manufactured by a company. For sterility test requirement of samples for most cases are 1+1+1+ or 2+2+2 (when content is less than 1 ml. or 50 mg.) in case of medical devices 4+4+4.
19.	Consideration of mentioning protocol in From 13 strictly in accordance with Rule 46.	It was decided that the Director, CIPL will look into the matter and examine the case.	Comments received. Decision has been taken to indicate protocols on reports issued in Form 13.

20.	Consideration of policy to be framed in respect of testing samples drawn and sent to the Govt. Analysts with very short expiry remaining.	The DCC decided the matter should be examined by a subcommittee.	The Commissioner, FDA, Maharashtra forwarded the report of the subcommittee which is placed for consideration. The relevant report may be placed for discussion in the next DCC.
21.	Consideration of provisions under which the approval of an Approved Testing Laboratory can be suspended or cancelled under the Drugs and Cosmetics Rules.	The DCC decided the matter should be examined by a subcommittee.	Provisions have already been made under the Drugs & Cosmetics Act and Rules.
22.	Consideration of the actions to be taken under the Drugs and Cosmetics Rules on the not of standard quality test reports declared by an approved testing laboratory.	The DCC decided the matter should be examined by a subcommittee. Made under item no. 45.	The issue has not been included in the Draft report of subcommittee on 30th DCC on guideline for approved Drugs Testing Laboratory. The Director CDL, Calcutta may please comment on the matter for further discussion.
23.	Consideration of the re-examination of the extent and conditions of exemption provided under point No.10 of Schedule 'K' for milk preparations and cereal preparations fortified with vitamins and minerals to be used for drugs.	It was decided that Sri K. C. Rastogi, Drugs Controller, U.P. will give a fresh write-up on the issue.	The matter may be taken up in the next DCC with expert comments from ADG (PFA).

24.	Consideration of inclusion of the word "Drugs Supplied" Point No.5 of Schedule 'K'.	It was decided that Sri K. C. Rastogi, Drugs Controller, U.P. will give a fresh write-up on the issue.	No such write up has been received from the Drugs Controller, U.P. Matter may be taken up in next DCC.
25.	Consideration of price control on diagnostic kits reagents.	The DCC decided the matter should be examined by a subcommittee.	The subcommittee could not meet and follow up the issue. The matter may be taken up in next DCC.
26.	Consideration of competent person for sale of drugs from motor vehicle under licence in Form 20BB and 21BB.	It was decided that the matter should be examined further as the sales under licence 20BB and 21BB, both are of restricted in nature.	Matter was referred to Commissioner, FDA, Maharashtra, for examination by the Expert Standing Committee. However, no report has been received in this regard. The matter may be taken up in next DCC.
27.	Consideration of amendment of Section 2 of Drugs and Cosmetics Act 1940 by replacing the words "Dangerous drugs Act, 1930" with the words "Narcotic Drugs and Psychotropic Substances Act, 1985."	Agreed for necessary Amendment.	The proposals is intended to be clubbed alongwith matter concerning NDA, Bill as and when the same is carried out under Drugs & Cosmetics Act amendment.
28.	Consideration of amendment of Section 27 A by replacing word "Section 17D" because Section 17 C is for 'Misbranded Cosmetics'.	Agreed for necessary amendments.	The proposals is intended to be clubbed alongwith matter concerning NDA, bill as and when the same is carried out under Drugs & Cosmetics Act amendment.
29.	Consideration of amendments of rules – Recall of drugs	The members opined that the loan licensing system is a subjudice matter.	Proposal to lay down modalities of procedure under Drugs & Cosmetics Rules 1945 for

	purported to be not of standard quality by the Govt. Analyst in case of loan licence manufacturers.	The matter should be taken up after confirming the Govt. stand on the loan licensing system.	effective recall of not of standard quality drugs where one of the agenda item (Item No. 2) is in 45th DTAB meeting held on 1/2/96. Members felt that immediate amendment under Drugs & Cosmetics Rules is not needed. However some effective administrative procedure may be taken up in this matter. Which is under progress. Also included as Central agenda in the next DCC.
30.	Consideration of maintaining control reference samples by the cosmetic manufacturers.	The matter has been referred to the Government Analyst Conference.	The matter may be again discussed in the next DCC.
31.	Consideration of extension of time period form 3 months to 6 months for the grant of licences to the applicants for manufacturing Ayurvedic or Unani drugs.	Matter should be referred to the Ayrvedic DTAB for their comments.	The matter is under examination by ASU DCC/ ASU DTAB.
32.	Consideration of the issuance of conclusive test reports by the PLIM Laboratory, Ghaziabad.	The matter has been referred to the Government Analyst Conference.	The matter may be taken up with Director PLIM, Lab. Ghaziabad for discussion in the next DCC.
33.	Consideration of classification on common testing facilities by the manufacturers having	The DCC decided the matter should be examined by a subcommittee.	The matter may be reconsidered in the next DCC.

	public testing laboratory.		
34.	Consideration of furnishing the price list by the manufacturers and their various agents to the State Drugs Controllers and drug dealers.	The DCC decided, the matter should be examined by a subcommittee.	The subcommittee could not meet and follow up the issue. The matter may be taken up in next DCC.
35.	Consideration of misuse of Oxytocin Injection B.Vet.C for getting excess milk from the cows and buffaloes.	Members felt that a guideline is needed to stop the misuse of Oxytocin Injection.	Guideline has been framed in the matter and circulated to All the State Drugs Controllers. In response, some of the State Drugs Controllers viz. Commissioner, FDA, Maharashtra, Drugs Controller, Kerala intimated that no misuse of Oxytocin Injection is reported in the respective State. However, reply from many of the State are yet to be received.
36.	Consideration of inclusion of Hyderabad airport under Rule 43A of the Drugs and Cosmetics Rules in respect of drugs imported by air to India.	Agreed for necessary amendment.	Draft proposal has been sent to Ministry of Health for final action.
37.	Consideration of import of cosmetics from Nepal through Rauxaul entry point under Rule 43 of Drugs and Cosmetics Rules 1945.	Agreed for necessary amendment.	Draft notification has already been issued for comments.
38.	Consideration for the	Agreed for necessary amendment.	45th DTAB constituted a subcommittee to

	amendment to para 12 of Part I Schedule M to prohibit the use of second hand containers and closuers in pharmaceutical preparations.		examine the whole issue.
39.	Consideration of storage of physician sample / free samples in depot / C&F premises and protection under Rule 65 (18) of the Drugs and Cosmetics Rules, 1945.	Agreed for necessary amendment.	Draft proposal to amend rule 65 (18) for inserting a proviso for stocking of Physician's samples/Free samples in depots and C&F premises is being sent to Ministry of Health for necessary action.
40.	Consideration of change of expiry date of Erythromycin Estoalate tablets under Schedule P of Drugs & Cosmetics Rules, 1945.	Agreed for necessary Amendment.	45th DTAB did not agree as it was felt that many other Drugs under Schedule 'P' are having longer life period than their formulations. Hence status quo is being maintained.
Special Agenda	Consideration of validity period of W.H.O. GMP certificate issued by State Drug Controllers	Members agreed to form a subcommittee to make necessary guide line for WHO certificate under WHO certification scheme.	Task force required to be framed. The matter may be again discussed in the next DCC.