MINUTES OF THE 30th MEETING OF THE DRUGS CONSULTATIVE COMMITTEE HELD ON 6th & 7th SEPTEMBER, 1995

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MINUTES OF THE 30TH MEETING OF THE DRUGS CONSULTATIVE COMMITTEE HELD AT NEW DELHI ON 6TH & 7TH SEPTEMBER, 1995

The Chairman while welcoming the members requested them to introduce themselves to **Dr. A. K. Mukherjee, Director Central Health Services (DGHS)**,who had kindly spared his valuable time and agreed to address the members of the Drugs Consultative Committee (DCC).

The Director General of Health Services while inaugurating the 30th DCC felt honoured to address the officers of State Drugs Control Organisations on vital issues, as enumerated by the Chairman, like regulatory requirements to strengthen the quality of pharmaceuticals; capacity validation; more emphasis on Herbal medicines; increased budget for States and Centre; importance of inspections and SOPs by the licensees; streamlining and rationalization of grant and approval of licences of notified drugs; control of Medical Devices and curbing the use and recycling of disposable syringes and needles.

DGHS commented that the scenario of drugs and pharmaceuticals in 1995 has undergone a change in terms of significant reduction in budget-deficit as investment has gone up manifold. Today, we are in a position to invest in much higher quantum and are attracting external investment in Drugs and Pharmaceuticals Sectors due to liberalization initiated by the Government. Many projects are being cleared in hospital development, services development, immunization through vaccines, etc.

The members should impress upon their Health Ministers the importance of expanding drug testing facilities, inspectorate staff and legal-cum-intelligence cell to ensure quality and unearthing of spurious and sub-standard drugs respectively. DG stated that in this direction the Centre has already embarked upon a Plan to assist States for modernizing their Pharmaceutical Testing Laboratories and augmenting inspectorate staff under Centrally Sponsored Schemes on 50:50 basis and is under ripe stage of finalization.

DG also informed the members that in pursuance of the Modified Drugs Policy, 1994, Central Government is contemplating strengthening of both Central and State Drugs Control and are under priority attention of the Government and we are preparing an ambitious plan to set up a much higher authority viz the National Drugs Authority (NDA) to plug weaknesses of the organizational set up and inadequate manpower and would try to tap financial resources from various agencies to fulfill this objective. Once NDA comes into force, the Central Govt. would share State Govt's burden in terms of quality assurance and render financial support. D.G. emphasized the need of such an authority as there are larger responsibilities and such responsibilities cannot be discharged because of inadequate number of manpower both at the State and Central level.

DG cited the example of Blood Banking System in the country with special references to motivation of voluntary blood donors and streamlining Blood Banking System with regard to proper collection, storage and distribution of blood as has been stipulated in the Central guidelines and should be strictly imposed under the supervision of Indian Red Cross Society. Further, efforts should be made to encourage and initiate facilities for blood components fractionation to prevent wastage of Human Blood and also to maximize the therapeutic efficacy of blood components by keeping them under different storage conditions. He stressed the need to evolve a correct mechanism for processing and distribution of safe blood by atleast the registered blood banking institutions.

DG asked the members for in-depth interaction and better coordination between the State and Central regulatory authorities with regard to the quality assurance and enforcement provisions of the statute so as to fulfill the aspirations of the consumer within the constraints of the existing frame work.

Finally, DG wished that deliberations by the members would yield definite recommendations which will plug many of the weaker areas and would help in proper enforcement for which we are answerable to the consumers.

The Chairman thanked the Director General of Health Services and informed the members at the outset that the Committee has invited specially intra and inter-ministerial officers to apprise the members on the steps being taken by them on certain agenda items which can be discussed in detail with them.

The Chairman stated that there is an increasing necessity of cooperation between Centre and State in the field of Quality Control and delivery of Health Services.

The Chairman continued with the idea on NDA. He stated that modified Drug Policy in 1994 provided more responsibility on us. Under this circumstances, we require more inspectorate staff, both in States and Centre. We must increase the activities of the State Drugs Control Authorities. Since our inspectorate staff are not much trained, we require more external experts. Like Japan and other advanced countries, we have definite requirement of a National Biological Centre (NBC), which will come up as a training institute and also provide standard operating procedures (SOP) for vaccines and biological units.

To achieve the required goal, the NDA will have two functional parts. The first part will cover up with the cess bill and the second part will cover up the extending portion over and above to the present Drugs and Cosmetics Act. The second part of the NDA bill will have 31 Sections and 10 chapters. Each chapter will be self-describing and each section will be highly illustrated to cover up herbal medicines, bulk drugs, GCP, Consumer Grievance Cell, OTC drugs and their control, etc. Thus, the second part being the extension of the present Drugs and Cosmetics Act will begin with chapter VI and cover up the modified Drug Policy. To achieve better success in the implementation, we will require 3000 Drugs Inspectors, out of which 300 will be in the Centre and the

remaining will be in the States Drugs Control Authorities. All the Drugs Testing Laboratories will be strengthened and six more testing laboratories will be started. Now 3 such testing laboratories are already in pipeline to start their functional activities. In order to have control over the interState movements of the drugs, the Centre will take up the power. The Drugs Controller (India) also elaborated that one percent cess of 6900 crores will be projected and there will be more emphasis on the inspection with the experts in different fields. A consolidated list of experts will be made. A guide for preparing Master formula will be made. The rationality of the formulations to be approved by the State Licensing Authorities will be elaborated.

The Chairman told that in the meeting several experts on various fields viz. BICP, Animal Husbandry, Ayurvedic Advisor, Homoeopathic Advisor have been requested to be present. The members had been requested to clarify their ideas in case they need in respect of any Agenda or as general discussions.

DMR (OA) Act – Curbing misleading advertisements and false claim by Herbal Oils.

(i) The members would recall that in the earlier meetings certain changes were proposed in the DMR (OA) Act. These changes were subsequently examined by the Sub-Committee of the DTAB and the Sub-Committee had recommended that necessary changes may be made under the relevant sections with reference to 'advertisement' and 'treatment' as well as addition / deletion to the Schedule incorporating list of diseases under the said Act. Whereas the Union Ministry of Health & F.W. is discussing the proposal to carry out changes approved by the DTAB, it is felt that to make the Act more effective and comprehensive, the members may discuss whether certain other changes in matter of prosecution, enforcement etc. is needed under the said Act so that the same could be also taken up in the forthcoming DTAB for further proposal to the Ministry of Health & Family Welfare. In this regard, I had also written to you in October, 1993, to create a Cell involving members from Consumer Associations of your State / Uts to scan the misleading advertisements on Drugs and Pharmaceuticals published in local Newspapers or advertised in Radio and T.V., who in turn, should bring it to the notice of the concerned authorities for taking remedial measures. I had also requested that local branch of IDMA/OPPI and Small Scale Sector may also be involved so as to bring to their attention whenever such unscrupulous advertisements are brought to your notice and the respective members responsible for releasing unethical / objectionable advertisements are hauled up. You may also give your suggestions in this direction for curbing the said menace.

(ii) In this regard I may also like to point out that repeated concern had been expressed at various fora including Parliament that certain Herbal oils are making false claim and misleading advertisements in the lay press as against ailments of short-fall in the human scalp including baldness and grey hair despite the fact that some of them are perhaps prohibited under the DMR (OA) Act or Schedule J. You may agree that such misleading advertisements and promising magic remedies for the promotion of their product is regarded as harzardous to the unwary consumers. I may propose that before

permitting such products at least their labels need to be screened and approved so that such misleading claims can be detected and suitable action on the appropriate stage as per Section (4) read with Section (7) of the said Act could be taken. Further the conviction obtained with regard to such cases should also be reported in the Newspaper.

After discussion, the members agreed with the Chairman to stay put to this menace and shall indicate their views concerning screening of labels before such items are approved for the sake of uniformity in the matter.

The Commissioner, FDA Maharashtra has proposed certain views for uniform adoption of Loan Licensing System for the entire country. The members are requested to go through and inform accordingly their view points concerning the matter.

Members may also give latest status on number of Loan Licences granted by them (category wise); number of samples drawn and declared sub-standard; action taken and prosecution launched' licences suspended / cancelled / permission withdrawn during the last ten years (w.e.f. 1.1.85 to 31.12.1994).

Shri Grover of IDMA being invited stated various anatomical details concerning advantages and disadvantages of Loan Licensing System. During discussion he furnished the following details which were collected by IDMA during the year 1991 :-

(i) There are about 16000 licensed manufacturers of Pharmaceutical formulations. Out of which, it is estimated that there were large manufacturers (200); medium and small scale (2800) and Loan Licences (13000).

(ii) If abolished, there may be retrenchment of about 500,000 employed / technocrats. At risk is also the sale turnover of about Rs.400 crores or 10% of the Pharmaceutical market collectively enjoyed by Small Scale Industry.

On being asked how many are functional Loan Licences (LLs) and how many are adhering GMPs especially in the SSI. Shri Grover stated that the exact figure can be had from State Drugs Controllers. However, there may be 3,000 SSI Units which may be catering to approx. 8000 LLs. The LLs is basically a contract between the larger units with the smaller units barring few exceptions. So far as grant or renewal of the LLs is concerned, Shri Grover clarified that the licences are being granted or renewed by SLAs only when they adhered to c-GMPs.

Reacting to the proposal of Loan Licensing System FDA, Maharashtra gave some statistical details on the basis of a survey carried out by them on quality of drugs being marketed by LLs. Shri Sanjay Narayan, Commissioner, informed that out of 6000 samples taken and tested them, during the period 1991-92 and 1992-93, 12% were declared not of standard quality and 68% of this figure were from those samples which were marketed by the Small Scale Sector. He contested that Small Scale Sector was not manufacturing quality drugs and hence were not adhering to c-GMPs. Shri Narayan proposed that IDMA may set up their own group of Inspectors and carry out self-auditing

so as to take necessary action to improve the c-GMPs concept by LLs as also the sagging image of SSI Units in this regard.

On being asked by the Chairman as to how many licensees in their State were devoid of laboratory in their own premises, SLAs stated that there are hardly any units which have not established their own lab.

The SLAs desired that they may be given some time to study the proposal mooted by FDA, Maharashtra. The Chairman requested them to go through the points mooted by FDA and let the Chairman know about their views together with the statistical details asked above to keep the Govt. abreast with the matter.

AS the members are well aware that disposable syringes and needles after being notified as devices have been classified under a separate Schedule M-III which lays down requirement of factory premises, their manufacture etc. Concern has been expressed both in the Parliament as well as in the Media that the items meant for 'Single use only' are being re-used / recycled by the unscrupulous persons to an extent that the public health is endangered despite the fact that such devices by its nomenclature have to be destroyed after its use. Similarly, date expired items which actually cease to be sterile beyond the expiry date are being sold / re-used after sterilizing them with Formalin. Needless to add that the contaminated syringes and needles could be carriers of Hepatitis and AIDS and could also cause certain bacterial infection and absesses. One of the ways to curb such menace may be to put them in Incinerator / needle destroying machine to prevent their reuse / recycling etc. SLAs may also consider inspecting Hospitals / Nursing Homes so as to draw the samples of these items to ensure their quality. Further, a list of manufacturers in each State may also be made available to the Govt. for information.

After discussion, the members agreed to convene a meeting of major Hospitals / Nursing Homes including inviting voluntary Associations so as to devise ways to curb the said menace. They also agreed to collect samples of these devices to ensure their quality.

During the last meeting, the members had on the basis of practical experience concerning applicability of the provisions of Rule 68A and 122 F had proposed certain structural changes to further streamline and rationalize the procedure for grant , renewal and approval of licences of notified drugs. The changes proposed were :

1. Forwarding the licences and list of items in triplicate and subsequent signature on them to enable CLAA to approve them.

2. Slight changes in the definition of Blood Banks.

3. Inclusion of separate definition of LVPs.

4. Mode of application, fees, forms and licences with respect to LVPs / Sera and Vaccines.

In this regard, the Govt. is taking expeditious steps to finalise the draft notification on which comments were received from some of you.

The members desired to further deliberate the operative aspects of CLAA. Under the circumstances, Zonal Officer West Zone detailed submission on mode of application, its receipt and subsequent joint inspection of the premises to decide if the application could be satisfactorily considered and recommended for the grant or renewal of licences by the SLA for approval by CLAA. The Zonal Officer also stated that so far as Blood Banks is concerned, State of Maharashtra has constituted a Plan Approval Committee which would meet once in a month to decide whether the application could be considered for the purpose.

The Chairman asked his Zonal Officer to circulate to all members the steps being followed by FDA Maharashtra for processing and disposal of applications with optimum time period for each of the components. The Chairman asked the members to comment upon it so that a 'check list of action' by the SLAs could be prepared for receipt of application, processing, joint inspection recommending thereof for approval by CLAA etc.

The Director, Drugs Control (W.B.) stated that as per provisions, the only authority empowered to take action is CLAA and any action taken by SLA would be illegal. SLAs may be given direct powers to suspend or cancel the licences even though such licences have been approved by CLAA. Further, there is no provision of joint inspection now being carried out is in good spirit.

FDA, Maharashtra also pointed out certain infirmities under rule 122-O, 68-A and Section 33P. The Commissioner stated that as per the existing procedure of licensing, the State Inspectors feel that they have least responsibility of implementation of provisions of the statute once the licences have been approved by CLAA.

The Chairman clarified that the concept of dual authority which apparently looks paradoxical is not agreeable. The concept of dual responsibility has the seal of the Union Ministry of Health and F.W. and may not be thought of strictly from the legalistic angle.

The Chairman also shared views of members if CLAA can delegate powers to his Zonal Officers under rule 122-L and 68-B. The Drugs Controller of W.B., J&K, Andhra Pradesh and Maharashtra pointed out that under the said rules, the delegation can only be made in terms of signing of the licences and may also thus not solve problems for curtailing period of delay of issue / approval of licences. They felt that the present arrangement at the level of Drugs Controller (I) should continue. However, Joint Commissioner Maharashtra was of the opinion to examine whether statuate could be amended to empower SLAs to suspend / cancel the licences once they have been approved by CLAA.

In the matter of suspension / cancellation by SLAs, Commissioner FDCA, Gujarat informed the House that they are already facing an appeal in the High Court on the action taken by them. Inspite of the fact that State Govt. defended the action taken by Commissioner by rejecting the appeal made to them by the accused firm. The Chairman requested the Commissioner to send the details of the matter as soon as it is decided by their High Court.

The members also discussed the need and involvement of an Expert in carrying out inspection of Blood Banks and LVPs as they felt that their supervisory staff is ripe enough to independently carry out this work. The Chairman clarified that these are specialized areas and hence an independent person's involvement is very much desired. Drugs Controller of Andhra Pradesh and W.B. supported the views expressed by the Chairman. It was, however, decided that those members who do not desire the services of an expert may send a write-up to CLAA.

Drugs Controller, Orissa desired that the list of experts may be enlarged so that more experts could be recommended on the Panel. The Chairman agreed to enlarge and screen the list once more names are identified by the SLAs.

After discussion, the members unanimously decided that the matter relating to CLAA (68-A and 122-F) may be sent to the Chairman of the Expert Standing Committee for (i) examination of amendments required (ii) to devise ways and means to cut down delay in the disposal / approval of the licences of Notified Drugs. The report submitted could be discussed and considered by the Committee.

The agenda items were thereafter taken up for discussion.

Item No.1 : Confirmation of the minutes of 29th D.C.C. meeting held on 6th and 7th January, 1994.

The minutes of the 29th Meeting of the Drugs Consultative Committee was confirmed by the members.

Item No. 2 : Statement of action taken on the minutes of 29th D.C.C. Meeting held on 6th & 7th Jan., 1994.

The Chairman explained the members of the action arising out of the minutes of the last D.C.C. Meeting. Members agreed with the statement of action. However, on certain items the following decisions were taken :

(a) **Whether tablets containing same active ingredient but having different colours can be permitted to be manufactured and packed in one single container under one batch number (Item No.27 of 29th D.C.C.)**

Earlier the Commissioner, FDCA, Gujarat sent a 'write-up' with the view that the same batch of finished tablets should not be marketed in different colours and shapes. The Director, Drugs Control West Bengal extended his views that the Committee may consider the marketing of one particular tablet with one type of colour and shape throughout the country. The Chairman stated that in such cases products patent relaxations are to be given. However, the matter was further discussed and agreed by the Commissioner, FDA, Maharashtra, the Drugs Controller, Andhra Pradesh and the Drugs Controller, Orissa. The Drugs Controller, Rajasthan stated that the norms should be for both coated and uncoated tablets.

Finally, the Chairman concluded that different colours and shapes for the same batch of a tablet should not be permitted for both coated and uncoated tablets.

Item No. 3 : 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 informed the members that the Sub-Committee constituted under Item (3) of the 28th D.C.C. has submitted the report and it is with the members for their perusal. The Chairman requested all the members to send their comments within three months' time to decide further course of action in the matter.

Item No. 4 : Consideration of the report of Sub-Committee on the proposal (i) to adopt norms for allocation and misuse of allocated narcotic drugs (ii) misuse of phensedyl cough linctus in certain States – Item NO. 11.41 and 60 of 29th D.C.C.

The members agreed with the report of the Sub-Committee to classify Codeine as Schedule 'H' Drug irrespective of its concentration thereby making it mandatory to print the Schedule 'H' requirements on the labels of products containing any amount of Codeine.

Item No. 5 : Consideration of the report of Sub-Committee on the proposal to take action on irrational and harmful drugs prohibited for sale under Section 26-A by one State where being manufactured and marketed by another State (Item No. 46 of 29th D.C.C.)

The members accepted the views of the Sub-Committee that the manufacturing, stocking and movement of the banned / irrational drugs will be monitored through the State Drugs Control machineries. The matter had been discussed further among the members regarding certain more clarifications.

The Chairman concluded the discussions with the remark that :

(a) When a new drug is approved by the Drugs Controller (I), the State Drugs Controllers should not permit the paedriatic formulations of the same without consulting the Drugs Controller (India).

(b) To minimize the movement of the banned / irrational drugs more publicity should be given.

(c) In case of any ambiguity in respect of banned / irrational formulations, the same should be referred to the Drugs Controller (India).

(d) In case of distinct movement of the banned / irrational drugs, legal actions should be taken and offender should be prosecuted.

(e) The banning time should be effected from the date of the notification.

(f) The State Drugs Controllers should constitute State FormulationCommittee to screen formulations from the angle of rationality, safety and efficacy and report to the Drugs Controller (India) of any irrational formulations moving in the market.

Item No. 6 : 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 list of repacking items has been discussed among the members. The Chairman considering the opinion of the members 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.

Item No. 7 : Consideration of the question to bring Ayurvedic, Unani and Siddha drugs under the purview of the sale licence – Item No. 45 of 29th D.C.C.

The Sub-Committee could not be formed as Shri A.G.Shah, Commissioner, FDCA, Gujarat did not agree to become the Chairman of Committee and Dr. P. D. Sethi, Director, CDL , Bombay who was convenor had retired. The matter is already under the purview of Ayurvedic DTAB Committee.

The Chairman, considering the opinion of the members concluded that the matter may be kept pending till final recommendations come from the Ayurvedic DTAB.

Item No. 8 : Consideration of the proposals –

a) **The period of sale licences should be for 10 years ending 31st Dec. of the last year.**

b) **The licence fees should be enhanced five times of the present amount.**

The proposals were taken up for discussion on the recommendation made by a Committee, which had been forwarded by the Secretary, Ministry of Medical and Health, Govt. of Rajasthan to reduce the load on the Drugs Control Machineries.

During the discussions many of the members were of the views to increase the period of sale licences, basically due to shortage of inspectorate staff for timely inspection of the sales premises. The Commissioner, FDA, Maharashtra is of the view that the period may be increased for 5 years only.

After discussion, the Chairman, concluded that the proposal should now be kept pending considering that proposal to augment inspectorate staff has been made under NDA Scheme and *status quo* be maintained in the matter.

Item No. 9 : Consideration of manufacturing of directly compressible grade bulk pharmaceuticals for tableting and capsulation.

The Commissioner, FDCA, Gujarat desired to have a guideline to manufacture Directly Compressible Paracetamol Granules for sale to the domestic market. The members including the Director, CDL, Calcutta were of the view that testing difficulties might come in such matter and standard specifications are to be developed.

Explaining further, the Chairman agreed that such permission should not be allowed for domestic market under the present circumstances.

Item No. 10 : Consideration of exemption from selling / distribution licences for product Vaseline white petroleum jelly I.P.

The members agreed to include the product, vaselilne white petroleum jelly I.P. to Schedule 'K' of the Drugs and Cosmetics Rules for necessary exemption under point No.26.

Item No. 11 : Consideration of inclusion of Buprenorphine in Schedule 'X' in the Drugs and Cosmetics Rules.

The Chairman informed that expert opinion is being generated by the Directorate in order to come to a logistic of preventing abuse yet not making availability of drugs difficult for terminal cases of concern. The possibility of allowing combination of Buprenorphine with other drugs so that such formula cannot be abused is under examination. Accordingly, the matter may be taken up at next D.C.C.

Item No. 12 : Consideration of coating of a combination tablet formulation where a single ingredient present required to be coated.

The members were of the views that the coating or uncoating of a tablet would depend on the individual and total physico-chemical characteristic of the drug present in the multicomponent formulations. Certain tablets may require coating and certain may not.

After discussion, the Chairman requested the Drugs Controller, Delhi Administration to give a write-up in the matter.

Item No. 13 : Consideration of stocking of drugs labeled as Physician's Samples in residential premises and unlicensed premises.

The members agreed that onus of proving the intention to stock such drugs is the responsibility of the person who is stocking. The Drugs Controller, Haryana and Andhra Pradesh, both suggested prosecution / legal actions in such matter.

The Chairman concluded that a guideline may be made by a sub-committee consisting of :

Commissioner, FDA, Maharashtra	-	Chairman
Drugs Controller, West Bengal	-	Member
Drugs Controller, Andhra Pradesh	-	Member
Shri K. C. Sharma, A.D.C.(I) South Zone	-	Convenor

He further stated that if required, we may restrict the quantities of the physician samples to be stocked by the Medical Representatives.

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

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 members felt that the issue may be studied after receipt of the said report.

Item No. 15 : Consideration of drugs declared as not of standard qulity by Government Analyst but declared standard quality by approved laboratory.

The Chairman agreed with the views of the members that the validity of the test reports issued by the Government Analysts has already been described under the Act. There is no such problem in this matter at the present circumstances as the Govt. Analyst reports supercede any other test reports.

Item No. 16 : Consideration of serving of summons on the accused of other States and obtaining constitution particulars, etc.

The members agreed after discussions that these problems are to be sought out administratively. Mutual co-operation among the State Drugs Controllers are required and needed in this area. Further, when constitution particulars are asked by one State Drugs Controller, a copy of the same may be endorsed to the Drugs Controller (India) for taking up the matter with the concerned State authorities for necessary action.

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

The Chairman suggested that the Drugs Inspectors and Police, both can file the prosecution under the DMR (OA) Act. The DMR (OA) Act is now under examination by a Sub-Committee. Any further clarification on the DMR (OA) Act may be kept pending till the sub-committee report is published.

Item No. 18 : Consideration of compounding of minor offences under the Drugs and Cosmetics Act.

The Chairman informed that a Sub-Committee already examined such cases and recommended certain actions. Accordingly, all these cases have been taken care in framing the provisions under NDA, which will be in extension of the present Drugs and Cosmetics Act and Rules.

Item No. 19 : Consideration of amendment to Section 25 (4) of the Drugs and Cosmetics Act to include the licensing authority to send sample under Section 23 (4) to CDL for test.

The members agreed that the provisions under Section 25 (4) provided the natural justice to the complainant and the accused. Such matter should be under the jurisdiction of the Court.

Item No. 20 : Consideration of Central assistance for improving the enforcement branch of Drugs Control.

The Chairman informed that for better mobility in the drug control machineries, Central assistance is under consideration for the enforcement branches of the State Drugs Control Administration.

Item No. 21 : Consideration of movement of irrational combinations of drugs.

The Chairman informed the members that in case of any specific movement of the banned / irrational drug, action should be taken by the State Drugs Control Authority. If required, prosecution can be done against the offenders. In case of any ambiguity the matter may be referred to the Drugs Controller (India). However, the Chairman told that the 'Anti-tubercular Kits' are not irrational.

Item No. 22 : Consideration of labeling of the individual unit of the Blood Collecting Kit – Baxter Brand.

The Chairman agreed alongwith the members that the single unit pouches in a complete Baxter Blood Collecting Kit can not be labeled with Date of Expiry. After the collection of Blood, the individual bag should be labeled with Date of Expiry.

Item No. 23 : Consideration to amend the general monograph of the capsule in the Indian Pharmacopoeia for addition of approved colours in the granules to be filled in capsules in patent and proprietory products.

The Director, CIPL intimated that the general monograph of the capsule in the Indian Pharmacopoeia has already been amended to provide for addition of approved colours.

The Chairman clarified that no further action is needed in this matter.

Item No. 23A:Consideration of laying down standards for raw materials of cosmetics.

The Chairman requested the experts from 'BIS' to explain the various aspects they are following in laying down the standards for the raw materials of cosmetics. BIS is the national standard body. Earlier it was ISI. Their main purpose is the formulation of national standards in different cases of activities from industrial items to consumer items. The BIS experts added that specifications are made for 23 finished cosmetics. 18 cosmetics are included in Schedule S of the Drugs and Cosmetics Rules. The manufacturer is supposed to comply with all the requirements. At present the BIS have established two standards – Dyes and Colours which can be used. List of chemicals which should not be used in manufacture of cosmetics and some chemicals which can be used in limited quantity. A list of permissible raw materials is being framed. The procedure for formulation of Indian Standard is made through the technical committees which include manufacturer, consumers, laboratories, etc. Once the BIS make the complete specifications, etc. of the finished cosmetics it indirectly cover the raw materials which should be used. List of raw materials not recognized is given under classifications of cosmetic Raw Materials, IS 4707 pt.II 1993. BIS has also laboratories at Sahibabad, Bombay, Chandigarh, Madras, Bangalore and Patna. These laboratories test those samples which are covered under BIS.

Item No. 24 : Consideration of interpretation of Para 10.1 (ii) Schedule M to clarify products not prepared under aseptic conditions required to be free from Pathogens, like Salmonella, E.Coli Pyocyanea, etc.

The Chariman alongwith the members decided that the tests for Salmonella, E.Coli, Pyocyanea, etc. are restricted to certain products only. A clarification has been made that the products have to be tested for freedom from pathogenic organisms if any of the inputs are susceptible for contamination.

Item No. 25 : Consideration of interoduction of campaign manufacturing principles as an option to dedicated facilities for corticosteroids and anti-neoplastic drugs.

The Chairman shared the views with the members that the action has already been taken in the matter. No separate facility is required for the corticosteroids. The antineoplastic drugs required separate facilities.

Item No. 26 : 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.

The Chairman agreed with the members that as British Vet Codex has become redundant, the Rule 124 A of the Drugs and Cosmetics Rules 1945 may be suitably amended to include the current edition of British Pharmacopoeia Veterinary in place of British Veterinary Codex.

Item No. 27 : 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 Chairman requested **Sri S. Consul, Joint Secretary, Deptt. of Chemicals and Petrochemicals** to explain the various provisions of Drugs Price Control Order as well as Drug Policy. Sri Consul narrated the DPCO, 1995 for better administration of the pricing system, including the Scheduled drugs, various forms, pricing structure, maintenance of records, penalties, action to be taken, etc. Mr. Consul told that for effective implementation following are to be done through the State Drugs Controllers :-

(a) When the prices of the formulations are fixed, the notification should reach to the Drugs Inspectors.

(b) Once the Drugs Inspectors get the list, they should check the retail outlets at random to see whether the price control is being implemented.

(c) Cases where the industry or the individual companies fail to carry out the provisions of DPCO, action has to be taken against them. DPCO is promulgated under the Essential Commodities Act.

(d) Sharing of the details of the production and the licences issued with the Department of Chemicals and Petrochemicals is important. The only possible way to get the total data is through the Drugs Controllers, since licences are issued and renewed by them. Information passed on regular basis would be very useful.

(e) Consumer movement in India is picking up slowly. We could involve some of the consumer groups in ensuring the proper implementation of price control. State Drugs Controllers can involve these social organizations like Lions Club, Rotary Club, etc. in assisting the Government machinery to see the laws are properly implemented. He further stated that under Essential Commodities Act, over-charging has to be punished and there is no provision for compounding of the offences under Act. For uniform implementation of the DPCO 1995 by different State Drugs Control Authorities, a sub-committee will frame the guidelines.

All members have been requested to send their queries to the Sub-Committee.

The Sub-Committee will be formed with the member BICP, Commissioner, FDA Maharashtra, Commissioner, FDCA Gujarat, DrugS Controller, Andhra Pradesh, Drugs Controller, J&K, Drugs Controller, Goa, Drugs Controller, Orissa and Dy. Drugs Controller (West Zone), Mr. Kaul of the Chemicals and Petrochemicals will be the convenor.

Item No. 28 : 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.

The Chairman along with the members decided that the matter could be brought to the notice of Ayurvedic DTAB and Homoeopathic Advisor before taking any action in this matter.

Item No. 29 : Consideration of the proposal to incorporate additional test regarding detection of Ethylene Glycol, Diethylene Glycol, Polyethylene Glycol in the monograph for Glycerin in I.P.

The monograph of Glycerin I.P. has been suitably amended in the forthcoming edition to include methods to detect impurities like ethylene glycol, diethylene glycol and polyethylene glycol. The Chairman told the members to take a note of this.

Item No. 30 : Consideration of the proposal to include corticosteroid in Schedule C(1) of the Drugs and Cosmetics Rules.

The Chairman agreed along with the members that the corticosteroids are not thermolabile drugs. Basically they are not considered under Schedule C(1) – of the Drugs and Cosmetics Rules.

Item No. 31 : Consideration of the proposal for providing mandatory provisions regarding testing of raw materials under Schedule 'M' of the Drugs and Cosmetics Rules.

The members felt that the sampling procedure for sterility test has been elaborated in the Pharmacopoeia and the finished products are also subjected to test for sterility.

The members desired that no further action is required to be taken in this matter.

Item No. 32 : Consideraton of the question whether animal feed preparations which are fortified with vitamins are to be drugs.

The members felt that the discussion should involve Sri D. Krishanan, Dy. Commissioner, Animal Husbandry Department, who is present as an expert.

Sri Krishnan stated that the matter should be examined on the basis of the composition and category of the item.

For detailed report on the matter, a sub-committee has been formed with Sri D. Krishnan, Drugs Controller, Goa, Commissioner FDCA, Gujarat and Dy. Drugs Controller, India, West Zone, Bombay.

Item No. 33 : Consideration of the question whether Aspartame can be permitted to be used as sweetening agent in pharmaceutical formulations.

The Chairman alongwith the members agreed to use Aspartame as a sweetening agent in the Pharmaceutical formulations.

The Director, CIPL informed that the monograph of Aspartame has been accepted in I.P. in the forthcoming edition.

Item No. 34 : Consideration of the proposal to provide a rule prohibiting the altering inscriptions on the containers, labels or wrappers of the Ayurvedic and Homoeopathic preparations.

The Chairman along with the members decided that the matter should be brought to the notice of Ayurvedic DTAB and Homoeopathic Advisor before taking any action in the matter.

Item No. 35 : Consideration of the proposal to identify a kit to be used by the laboratory attached to the Blood Bank for carrying out AIDS test.

The Chairman intimated that sensitivity and specificity both are the criteria to identify the kits for HIV tests in the Blood Bank. It is better to utilize the NACO guidance in this matter.

Item No. 36 : Consideration of the proposal to amend Rule 46 of the Drugs and Cosmetics Rules for incorporating words "or an officer authorized by him" after the words, "Government Analyst".

During the disussions among the members the Drugs Controller, Goa referred that such proposal had been made on the basis of certain remarks made by a court in relation to a prosecution case handled by him.

The members desired that the complete prosecution case along with the judgement may be examined before taking any decision on the matter.

The Chairman agreed along with the members that the Drugs Controller, Goa should send the judgement of the case for examination.

Item No. 37 : Consideration of the question to ban the use of Saccharin in paediatric preparations.

The Director, CIPL, Ghaziabad informed that in the Fourth Edition of I.P. the cautionary remarks has been included under the monograph Saccharin that "not to be allowed in paediatric preparations".

Item No. 38 : Consideration of imported raw materials of B.P. and USP standards.

The Chairman agreed along with the members that imported raw materials of B.P. and USP standards should pass I.P. standard, if such monographs are in I.P. The FDA Commissioner, Gujarat stated that raw materials like Calcium Pantothenate is in U.S.P. and I.P. both. Though it passes U.S.P. it may fail certain tests in I.P.

The Director, CIPL will look into the matter and examine the case.

Item No. 39 : Consideration of the action to be taken by the Govt. Analyst when transfusion fluid samples are found with visible fungal growth in containers.

Considering the nature and importance of the problem, the members desired to keep the agend pending for discussing in the forthcoming Govt. Analyst Conference.

Item No. 40 : Consideration of batch size for test or sterility by the Govt. Analysts to test the samples drawn by the Drugs Inspectors.

Considering the nature and importance of the problem, the members desired to keep the agenda pending for discussion in the forthcoming Govt. Analyst Conference.

Item No. 41 : Consideration of mentioning protocol in From 13 strictly in accordance with Rule 46.

Considering the nature of the agenda, the members desired to keep it pending for discussion in the forthcoming Govt. Analyst Conference.

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.

The members agreed that guideline should be framed in this matter.

The Chairman told that a Sub-Committee consisting of Commissioner, FDA Maharashtra, Commissioner, FDCA Gujarat, Drugs Controller, West Bengal and Drugs Controller, Orissa may give the guidelines in the matter.

Item No. 43 : Consideration of the minimum area to be provided by a Blood Bank below the limit of the area (100 sq. mt.) as specified under the Drugs Rules.

The members are of the view that any such particular case may be solved under the discretionary power of the licensing authority.

No further illustrations are required in the matter.

Item No. 44 : Consideration of the mimimum staff to be provided in a Blood Bank below the limit of the total staff (5) as specified under the Drugs Rule.

The members are of the view that any such related specific case may be solved under the discretionary power of the licensing authority.

Item No. 45 : Consideration of provisions under which the approval of an Approved Testing Laboratory can be suspended or cancelled under the Drugs and Cosmetics Rules.

The Chairman along with the members agreed to constitue a Sub-Committee of the following members to examine the issue – Commissioner, FDA, Maharashtra, Chairman, Commissioner, FDCA, Gujarat, Member, Drugs Controller, Delhi, Member, Drugs Controller, Tamil Nadu, Member, Drugs Controller, Jammu & Kashmir, Member, Director, CDL, Calcutta, Member.

Item No. 46 : 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 issue will be examined by the Sub-Committee made under Item 45.

Item No. 47 : 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.

The Chairman along with the members agreed that Sri K. C. Rastogi, Drugs Controller, U.P. will give a fresh write-up on the issue.

Item No. 48 : Consideration of inclusion of the word "Drugs Supplied" Point No.5 of Schedule 'K'.

Sri K. C. Rastogi had been requested to examine the matter and if needed to cover up the same in his write-up on Schedule 'K' as mentioned under Item No.47.

Item No. 49 : Consideration of the implementation of laws for brand name confusion.

The matter had been referred by the Drugs Controller, Himachal Pradesh that due to similarities of the brand names, sometimes the chemist might confuse in reading the prescription and giving the substitute drug.

The members felt that existing provisions of the Drugs and Cosmetics Act and Rules are sufficient to deal such matter.

Item No. 50 : Consideration to provide funds for augmentation of testing facilities in the drugs testing laboratory in the States.

The Chairman informed that the NDA should take care of the matter. He stated that all the Drugs testing laboratories would be strengthened and six more testing laboratories would be started as and when NDA comes in force.

Item No. 51 : Consideration to adopt BIS Specification for medical devices as per the new amendment.

The members agreed that as per amendments vide notification No.109(E) dated 22.2.94, the medical devices has to conform to BIS standard and the amendment notification was sent to all State Drugs Controllers in Sept., 94 for implementation. Regarding the earlier stock already in the market, not upto the BIS standard should be withdrawn.

Item No. 54 : Item No. 52 to 54 proposed by the Drugs Controller, Kerala could not be discussed as the concerned member was not present.

Item No. 55 : Consideration of proposal seeking alteration of combinations containing (1) Dicyclomine HCL (2) Dextropropoxyphene HCL and (3) Acetaminophen under the brand names of Spasmo-Proxyvon and Parvon Spas mfd. By M/s Wockhardt Limited, Aurangabad and M/s Jagsonpal respectively due to their lethal abusive properties.

The Chairman informed that the formulations are being examined by the experts to take necessary action in the matter.

Item No. 56 : Consideration of price control on diagnostic kits reagents.

The matter may be referred to the Sub-Committee formed under Item No.27.

Item No. 57 : Consideration of competent person for sale of drugs from motor vehicle under licence in Form 20BB and 21BB.

The members felt that the matter should be examined further as the sales under licence 20BB and 21BB, both are of restricted in nature.

Item No. 58 : Consideration of bathing bar under the provisions of Drugs and Cosmetics Act and Rules thereunder.

The Chairman requested the experts from BIS to explain BIS Standards of Bathing Bar. The BIS experts expressed the view that the standards of bathing bar were intended to be made based on performance criteria. In the toilet soap, it is important to see that it should produce good lather and should suit the skin. Accordingly, a sectional committee dealing with toilet soap started working on it. In 1992, IS 13498 specification for bathing bar provided that the product containing acceptable surface active agents could be used for bathing purpose.

In the earlier meetings it was recommended by the DCC to include fatty matter and synthetic detergents and limits should be specified for both. Manufacturers were asked to generate data and produce before the sub-committee. They are likely to give the data by 3rd week of September. The Sub-Committee will meet again. The composition of bathing bar is a mixture of fatty matter and synthetic detergent. The lowest grade of toilet soap should have minimum 60% TFM.

Item No. 59 : 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."

Members agreed for necessary amendment.

Item No. 60 : Consideration of amendment of Section 27 A by replacing word "Section 17D" because Section 17 C is for 'Misbranded Cosmetics'.

Members agreed for necessary amendments.

Item No. 61 : Consideration of amendments of rules – Recall of drugs purported to be not of standard quality by the Govt. Analyst in case of loan licence manufacturers.

The members opined that the loan licensing system is a subjudice matter. The matter should be taken up after confirming the Govt. stand on the loan licensing system.

Item No. 62 : Consideration of maintaining control reference samples by the cosmetic manufacturers.

The members felt that the maintenance of control reference samples in case of cosmetics is also one of the important aspects of cosmetic manufacturing. However, the quantum of the samples corresponding to the category of the cosmetic items should also be considered in respect of this matter.

The members felt that the matter should be discussed in detail in the forthcoming Government Analyst Conference for taking further necessary action.

Item No. 63 : 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.

Members felt that the matter should be referred to the Ayurvedic DTAB for their comments.

Item No. 64 : Consideration of issuing the validity certificate of licences to manufacture for sale of drugs under the provisions of Drugs and Cosmetics Rules where the services of CLAA are required.

Members after discussion came to the conclusion that the State Licensing Authority may issue such validity certificate under intimation to the Central Licence Approving Authority (CLAA) provided that nothing adverse is against the record of the licensee till the date of issue of such certificate.

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

Members felt that it is necessary to give conclusive remarks alongwith the testing data in the test report issued by the PLIM Laboratory, Ghaziabad. Government Analyst should specifically mention regarding the sample as of standard quality or not.

It is further decided that the mode of reporting in the test report may also be discussed in the forthcoming Government Analyst Conference.

Item No. 66 : Consideration of classification on common testing facilities by the manufacturers having public testing laboratory.

The issue will be examined by the Sub-Committee formed under agenda Item No.45.

Item No. 67 : Consideration of compounding of offences under Drugs & Cosmetics Act and Rules thereunder.

The matter has already been discussed under Item No. 18.

Item No. 68 : Consideration of renewal of licences of LVP and Blood Bank units through independent inspections by the SLA.

After discussion, the members agreed that proper coordination should be maintained and information should be sent for joint inspection well in advance to the Central Authority to renew the LVP units / Blood Banks preferably with experts.

Item No. 69 : Consideration of clarification of Rules 65 (11A) of the Drugs & Cosmetics Rules in respect of sale of drugs.

Members felt that specific problems relating to this issue should be focused for clarification. So far the selling of Schedule H and Schedule X drugs are concerned, the existing rules are sufficient to tackle the situations under the Drugs and Cosmetics Act and Rules.

Item No. 70 : Consideration of furnishing the price list by the manufacturers and their various agents to the State Drugs Controllers and drug dealers.

The matter was discussed and it has been decided that the issue will be taken up by the Sub-Committee formed under Item No. 27.

Item No. 71 : Consideration of asking reference standards by the Govt. Analyst from the Drugs Inspectors on samples drawn by them for test and analysis.

The members felt that Govt. Analysts reference standard from the Director, Central Drugs Laboraotry, Calcutta or in alternative they may address the concerned State Drugs Controller for the said reference standard. In this matter, the Director, CDL, Calcutta intimated that reference standard is becoming very costly and he requested that once a

laboratory gets the reference standard from CDL, Calcutta, he should maintain the same and prepare its own reference standard for further use.

Item No. 71A :Consideration of misuse of Oxytocin Injection B.Vet.C for getting excess milk from the cows and buffaloes.

The members agreed that the Chairman would write to the Commissioner, Animal Husbandry, Department of Agriculture to take his view point in this matter.

Considering the importance of the matter, it has been felt that a guideline is needed to stop the misuse of Oxytocin Injection.

Item No. 72 : Consideration of description given in the monograph of the drugs in the Pharmacopoeia can be taken as standard.

The members had been informed by the Director, CIPL, Ghaziabad that in the forthcoming issue of Indian Pharmacopoeia (4^{th} edition), the 'description'has been taken as a part of the standard.

Item No. 73 : Consideration of examination of the Secton 22 (2A) of the Drugs and Cosmetics Act, 1940.

Members felt that for implementation of the provisions narrated under Section 22 (2A) of the Act, the certified copies of the seized documents may be kept / returned to the persons from whom the same had been taken. The original copies may be retained for the production in the court.

Item No. 74 : Consideration of uniformity in the weeding out of irrational formulations of drugs.

The matter has been already discussed under Item No.5.

Item No. 75 : Consideration of more training facilities by CDSCO for inspectorate staff for the inspection of blood bank.

The Chairman informed that the matter has already been taken up for providing training to the Drugs Inspectors not only on blood bank inspection but also on various other discipline like Large Volume Parenterals, Vaccine units and other drug manufacturing units.

A specific scheme has been kept under NDA for this purpose.

Item No. 76 : Consideration for formulation containing Codeine and Promethazine Hydrochloride in Schedule H drugs.

Chairman intimated that the matter has already been taken up by the Directorate.

Item No. 77 : Consideration of inclusion of Hyderabad airport under Rule 43A of the Drugs and Cosmetics Rules in respect of drugs imported by air to India.

Considering the regular importation and exportation of drugs, it has been decided by all the members, Hyderabad airport should be declared as one of the places for import under the Drugs and Cosmetics Rules.

Item No. 78 : Consideration of import of cosmetics from Nepal through Rauxaul entry point under Rule 43 of Drugs and Cosmetics Rules 1945.

Considering the requirement of the import of toilet soaps and cosmetics as recommended by the Ministry of Commerce, it has been decided that Rauxaul will be one of the entry point for the cosmetics under the Drugs and Cosmetics Rules.

Item No. 79 : Consideration for the amendment to para 12 of Part I Schedule M to prohibit the use of second hand containers and closuers in pharmaceutical preparations.

The members agreed for the amendment of the relevant part of the Drugs and Cosmetics Rules to prohibit the use of the second hand containers and closures in Pharmaceutical preparations.

Item No. 80 : 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.

Members agreed for the amendment of the Rule 65 (18) to protect the storage of physician samples / free samples in depot of the C&F premises.

Item No. 81 : Consideration of change of expiry date of Erythromycin Estoalate tablets under Schedule P of Drugs & Cosmetics Rules, 1945.

Members agreed to amend the concerned column under Schedule P to provide the expiry date of Erthromycin Estolate tablet as 36 months in place of 24 months.

SPECIAL AGENDA

CONSIDERATION OF VALIDITY PERIOD OF W.H.O.

GMP CERTIFICATE ISSUED BY STATE DRUG CONTROLLERS

Commissioner, Food and Drugs & Control Administration, Gujarat stated that usually they issue WHO Certificate for a period of 2 years and desired to know the views of DCC whether the validity of certificate will expire immediately after two years or can remain valid for certain more period of time. After discussion, it was decided that the WHO – GMP Certificate will be valid for another 3 months and the firm may apply for its revalidation within that period.

Th Chairman desired to form a sub-committee which will prepare a guideline for WHO Certification Scheme. The Sub-Committee will consist of :-

1.	Drugs Controller (India)	-	Chairman
2.	Commissioner, Food & Drugs Administration, Gujarat	-	Member
3.	Director, Drugs Control, Andhra Pradesh	-	Member
4.	Drugs Controller, Uttar Pradesh	-	Member
5.	Director, Drugs Control Tamil Nadu	-	Member
6.	Director, Central Drugs Laboratory	-	Member
7.	Dy. Drugs Controller (India) Headquarters, DGHS	-	Member Convenor

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Annexure – I
(Item no. 2 of the 30th meeting)

Statement showing the action taken on the decisions taken at the 29th Meeting of the Drugs Consultative Committee held in New Delhi on the 6th & 7th January 1994.

NO.	SUBJECT DISCUSSED	DECISION TAKEN	ACTION TAKEN
(1)	(2)	(3)	(4)
1.	Curtailing of the number of licences required for stocking distribution and sale of drugs – reports of subcommittee formed under 28th DCC-Item No. 3.	Since the report has received by the members on the day of discussion the Chairman requested the members to furnish their comments within 2 months to decide further course of action.	Further discussions may be held on the report.
2.	Proposal to fix limits concerning net volume / content in respect of P&P preparations under Schedule	The Chairman and members of the DCC, agreed to refer to IP Committee the anamoly of not prescribing the test on net content / volume in liquid oral	A separate appendix containing "contents of package dosage forms" have been approved by the I.P. Committee.

	'V' of Drugs & Cosmetics Rules, 1945.	preparations and to take suitable decision to mention the same in the forthcoming new edition.	
3.	Consideration of the report of the Expert Standing Committee constituted under 28th DCC regarding : (A) Minimum area with regard to retail sale of drugs under Rule 64. (B) Provisions for having separate area for powder prepartions meant for external and internal use under Schedule 'M'.	The DCC recommended that an area not less than 15 sq.m., wherever licences in respect of both wholesale and retail are granted in the same premises, should be specified under Rule 64 in addition to the area already specified in the said rule in accordance with the Schedule 'N'. For retail licence in Form 20 and Form 21 the area should be not less than 10 sq. mt. The DCC recommended that suitable changes in the form of 'proviso' or as a 'Note' at the end of Schedule 'M' may be inserted that external preparation and preparation used internally should not be prescribed in the same action.	Publication of Draft notification is being contemplated. Publication of Draft notification is being contemplated.
4.	Amendment to Rule 85 Proposal to amend empowering licensing authorities to direct manufacturers to stop	The Chairman informed the members that 43rd Meeting of DTAB on the recommendations of Drugs Consutlative Committee considered the proposal to include a provision empowering regulatory authorities to direct	Final notification in the matter is under progress.

	manufacturing and to destroy drugs considered unfit for human use.	manufacturers to stop manufacturing and destroy drugs considered unfit for use especially in those cases where legal action is not contemplated.	
5.	To check misuse of "Phensedyl Cough Linctus" in certain States.	The DCC decided the matter should be examined by a sub-committee.	Subcommittee Reports are in the agenda of 30th DCC.
6.	To include bathing bars under Schedule 'S' of the Drugs & Cosmetics Rules, 1945.	The DCC recommended the bathing bars may be included in Schedule 'S' on the basis of the standards already specified for their publication IS:13498:1992	The matter is under consideration as 'BIS' is contemplating to finalise the standards of Bathing Bar.
7.	Proposal for prohibition to market certain anti-diarrhoeal preparations under Section 26-A of the Drugs & Cosmetics Act, 1940.	The DCC recommended that the combinations proposed from (a) to (f) of the agenda may be banned under Section 26-A of the Act keeping in view the proposal made by Drugs Controller, West Bengal that the word "Paediatric" wherever occurring may be replaced with the words "liquid oral diarrhoeal".	Final notification GSR 731 (I) dated 30/9/94 has been published in the matter.
8.	Proposal of streamlining of patent & proprietary oral rehydration salts (ORS).	The Chairman informed that the Expert Committee recommended prohibition on marketing of P&P ORS except those conforming to the parameters stated under (a) to (c) of the agenda. The Chairman also agreed to send	Final notification GSR 57 (E) dated 7/2/95 has been published in the matter.

		circulars on conversion procedure of millimoles to grams to all the members as a guideline.	
9.	Proposal to make amendments in the notification No. GSR-69(E) dated 11.2.91 regarding fixed dose combinations (FDC) of anti-helmintic with cathartic / purgative.	Recommendation made that the following clause may be inserted 'FDC of anthelmintic with cathartic / purgative except Piperazine and Santonin or any drug acting identically'.	Final notification GSR 848 (E) dated 7/12/94 has been published in the matter.
10.	Amendment to Notificaiton No. GSR 49(E) dated 31.1.84 banning fixed dose combination of Tetracycline with Vitamin C.	There was a unanimous opinion of the members that fixed dose combination of any of the Tetracycline group with Vitamin C should be banned.	Final notification GSR 848 (E) dated 7/12/94 has been published in the matter.
11.	Adoption of standards for ophthalmic preparations laid down under Schedule FF for Homoeopathic ophthalmic preparations. (Rule 126A)	The members agreed that there seems to be no need to provide a new Rule but appropriate insertions may be made in Rule 126A itself which already exist for allopathic system of medicines.	Draft notification 96 (E) dated 24/2/95 has been published for comments. Final notification is under progress.
12.	To enlarge list of cosmetics under Schedule 'S' to the Drugs & Cosmetics Rules.	The members unanimously agreed to include the listed items for inclusion in Schedule 'S' to the Drugs & Cosmetics rules as per the specifications formulated by the BIS.	Draft notification 674 (E) dated 6/9/94 has been published for comments. Final notification is under progress.
13.	Consideration to adopt BIS as statutory marking for	The Chairman exhorted the members to examine whether Scheme of Cosmetics	Individual State to decide whether to adopt the (BIS) scheme subject to the consent of the

	cosmetics.	Testing Laboratories as available under BIS can be utilized to examine testing of cosmetics as the facilities available under drugs control administration is inadequate and requires improvement. Members of individual State opted to decide whether to adopt the (BIS) scheme subject to the consent of the industry.	industry.
14.	Whether tablets containing same active ingredients but having different colours can be permitted to be manufactured and packed in one single container by assigning one batch number.	The Chairman also requested FDCA, Gujarat to give a write-up regarding marketing of formulations containing different colours but same ingredients. However, Chairman told the members that the same batch of finished products should not be marketed in different colours.	The Chairman also requested FDCA, Gujarat to give his opinion. He is of the view that the same batch of finished products should not be marketed in different colours.
15.	Consideration of the question as to whether drugs can be permitted to be repacked in the pack sizes other than those specified by Drugs Controller (India) (vide Circular No. 19013/4/80-D dated 12.3.82)	The Chairman agreed with the members that in order to update the list a subcommittee may be constituted.	The report of the subcommittee has been received and is with the agenda of 30th DCC for discussion.
16.	Proposal to amend Rule 96 to include assignment of date of expiry (DOE) to bulk drugs under Scheduel 'P' of the	The DCC proposed to amend Rule 96 (vii) of Schedule 'P' of the Drugs & Cosmetics Rules.	Draft notification 94 (E) dated 24/2/95 has been published in this regard. Further action is under progress.

	Drugs & Cosmetics Rules, 1945.		
17.	Consideration of the question whether colour and sweetening agents can be permitted to be used in the preparation of oral rehyderation salts (ORS) bicarbonate / citrate which are official in IP Addendum –II.	The Chairman clarified that the matter shall be referred to I.P. Committee for further examination.	The I.P. Committee did not agree to the proposal
18.	Consideration of the question whether the cough preparations can be permitted to be manufactured with the parameters other than those which had been recommended under Item NO.14-A(XIV) in the 26th DCC Meeting.	The Chairman requested the Drugs Controller, Goa to give details of such cough preparations.	List of irrational cough preparations sent by the Drugs Controller, Goa is placed for discussion.
19.	Laying down guidelines for plant and machinery required for manufacturing diagnostic reagents together with their labelling requirements.	The Chairman proposed to examine the matter through a subcommittee along with a member from 'BIS'.	Subcommittee has been formed under the chairmanship of Commissioner, FDA, Maharashtra and DDC(HQ) as convenor member. The report on GMP is placed for the consideration.
20.	Consideration of the question regarding action to be taken for serious cases of drugs reported to be sub-standard.	The Chairman requested the Food & Drugs Controller, Gujarat to furnish the details of the copy of the judgement together with the copies of the complaint and counter affidavit filed in	A copy of the judgement of Hon'ble High Court, Gujarat as received from the Commissioner, FDCA, Gujarat is placed for consideration and discussion.

		the case.	
21.	Laying down norms concerning advertisements on T.V. over-emphasising results of Ayurvedic & OTC drugs.	The matter will be taken up for clarifications from various authorities.	Doordarshan has been requested to clarify their procedures for telecasting advts.
22.	Sale Licences for Ayurvedic, Unani, Siddha drugs.	After discussion members agreed to form a subcommittee under the convenorship of Dr. P.D. Sethi, Director, CDL, Bombay.	Subcommittee could not be formed to discuss the issue. The item has been referred under agenda of 30th DCC.
23.	Irrational and harmful drugs prohibited from sale under Section 26-A by one State but were being manufactured and marketed by another State.	The Chairman alongwith the members agreed to form an expert committee to examine the matter with Commissioner, FDA, Maharashtra, as Chairman and DDC(I) (SZ) as convenor.	The report of the committee has been received and is under Agenda no. '5' of 30th DCC.
24.	Framing uniform policy pending abolition of loan licensing system with regard to manufacture of drugs in units other than the parent firm.	Commissioner, Food and Drugs Administration, Maharashtra to give a write-up on the manner of grant or renewal of loan licences in his State so that the same could be circulated for information and necessary perusal by the other members.	Received the write up with the comments to circulate the same to all the State Drugs Controller for discussion.
25.	To express content of liquid oral preparations in terms of 5 ml. under Rule 96 of Drugs and Cosmetics Rules, 1945.	The Chairman and the members desired that necessary amendment to entry (a) to clause (iii) of subrule (1) to Rule 96 may be carried out so that the words "or multiple thereof" where deleted. This	Draft notification has been published in this matter. The Final notification is under progress.

		omission would only allow liquid oral preparations in terms of 5 ml. only.	
26.	Uniform guidelines in making accused for contravention of the provisions of Drugs and Cosmetics Act, 1940 and Rules thereunder.	The Chairman requested Drugs Controller, Delhi and FDCA, Gujarat to give a write-up on the matter for further examination.	The Write-up as received from the Drugs Controller, Delhi has been placed for discussion.
27.	Criteria for herbal cosmetics	The Chairman requested for a detailed write up on the matter from BIS.	The extract from the write up received from 'BIS' is furnished below: "No Indian standard on herbal cosmetics has for been published. It is, however felt that herbal cosmetics in addition to herbals use many other raw materials which are used in the manufacture of non herbal cosmetics. These raw materials should conform to relevant Indian standards whenever such standards are available. Similarly Part I and Part II of IS 4707 should equally apply to herbal cosmetics also. Many of the finished cosmetics standards include performance requirement which in our opinion can also be applicable to herbal cosmetics. However it will be very difficult to prescribe limits for minimum or maximum usage of different herbs for various cosmetics in view of inadequate information available on this subject. It is also felt that your office may consider this issue on the similar lines as is

			being done for ayurvedica medicines". The matter may be further discussed in the DCC.
28.	Omitting provision relating to setting up of testing laboratories by the cosmetic manufacturers under Schedule M-II under Drugs and Cosmetics Rules, 1945.	The members felt that cosmetics manufacturer should continue to be insisted upon to provide a testing laboratory in their own premises. However, the provisions made under the Schedule M-II may be omitted and sub-rule (5) to Rule 139 havnig clauses (i) and (ii) should be substituted appropriately so that each licensee has testing facility in its own premises.	Draft notification 94 (E) dated 24/2/95 has been published in this regard. Further action is under progress.
SUBJECT			
66	Revision of Schedule H	The report of the subcommittee was considered at 43rd DTAB meeting to enlarge to include some more drugs in Schedule H.	Final notification to publish Schedule H is under progress.
67	Revision of Schedule R to bring standards of condoms at par with W.H.O.		Final notification has been sent to the GOI press.
68	Definition of RMP under Clause 9iii) of Rule 2 (ee)	The 27th DCC recommended to delete RMP's from Rule 2 (ee). 44th DTAB desired that before any action is taken to publish draft notification, out off date in respect those person who may have been already registered may be accorded	The matter is under consideration for publishing draft notification.

		protection further in view of the judgement of the Rajasthan High Court and the opinion expressed by M.C.I. it may not be feasible to specify any cut off date before publishing draft notification.	
69	Amendment of Rule 85 to provide powers to licensing authority to stop manufacture or destroy drugs.	-	Draft notification has been published. The final notification is under progress.
70	Deletion of word 'approved' before expert staff in Form 25 F, 26, 26 A, 26 F, 28, 28 A and sub para (1) of Para 10 (1) of Schedule M.	-	Draft notification GSR 730 (E) dated 30/9/94 has been published. The final notification is under progress.
71	Deletion of corticesteroios from Para 10.2 of Schedule M.	-	Draft notification GSR 730 (E) dated 30/9/94 has been published. The final notification is under progress.
72	Qualification of Govt. Analyst	-	Draft notification GSR 754 (E) dated 18/10/94 has been published. The final notification is under progress.
73	Amendment of Rule 85 (E) reg. inspection before grant of a licence. Addition of a new sub-rule after 139 (A) for rejection of application in form	-	Draft notification GSR 541 (E) dated 28/6/94 has been published. The final notification is under progress.

	31 or 31 A.		
74	Amendment of Rules 65 (5) and 65 (18)	-	Draft notification GSR 511 (E) dated 15/6/94 has been published. The final notification is under progress.
75	Amendment of Schedule V in respect of (P&P) Vitamins preparations meant for use of animals.	44th DTAB constituted a special committee to lay down individual Vitamins content for Vet. Preparation under Schedule V.	Steps to take further action to publish draft notification will be discussed in the next DTAB meeting.
76	Amendment of Schedule M for large volume parenterals.	44th DTAB constituted a special committee to lay down norms for different types of LVPs technology for glass bottles FFs plastic containers and plastic pouches.	The report as and when submitted would be discussed in the next meeting of DTAB.
77	Inclusion of diagnostic reagents and kits in Schedule C & C(1).	Draft notification published for the purpose could not be finalised for the reason that the subcommittee of DCC constituted for the purpose is also examining the inclusion of detailed list under the said Schedules.	The report of the committee is being discussed in the 30th DCC meeting for further action in the matter.
78	Consideration to amend the Drugs & Cosmetics Rules to streamline the procedures for grant and renewal of licences in respect of drugs like Blood and Blood Components, Sera and Vaccine and LVP for	New definition of Blood Bank has been proposed. Licences in triplicate alongwith the list of items duly signed by SLA has been proposed under Rule 122 F (5) and 68 A for forwarding to CLAA.	Final notification is under process.

	which Central Govt. is also a Licence Approving Authority.		
79	Prescribing fees and Forms separately for LVPs/SERA and Vaccines under Rule 75,76,77,78,81,83,84 A and Schedule 'A'.	Form 28 is clubbed form for SVPs and LVPs and Vaccine and Seras. There is no definition for LVPs. No separate renewal certificate or mode of application is prescribed for LVPs and Sera and Vaccine.	Final notification is under process.
80	Weeding out of irrational formulation of Dover's Powder.	-	Final notification published vide GSR 111(E) dated 22/2/94.
81	Amendment of Rule 85 (E) for qualification of technical staff for manufacture of Homoeopathic medicines.	-	Final notification published vide GSR 812 dated 14/11/94.
82	Adoption of IS4707: 1988 (Pt. I) as Cosmetics colours under Schedule Q.	-	Final notification published vide GSR 811(E) dated 14/11/94.
83.	Amendment of item 5 (A) of Schedule K reg. voluntary subscription.	-	Final notification published vide GSR 812(E) dated 14/11/94.
84	Amendment of Rule 71 qualification for manufacture of veterinary drugs.	-	Final notification published vide GSR 93(E) dated 24/2/95.

85	Amendment of Rule 54 (A) to add 'Cosmetic' after 'drug'.	-	Final notification published vide GSR 850(E) dated 7/12/94.
86	Amendment of Form 13 reg. seals on the sample potion. Amendment of Rule 58 A (3).	-	Final notification published vide GSR 59 (E) dated 7/2/95.
87	Amendment to Rule 97 (2) to indicate 'for external use only'.	-	Final notification published vide GSR 850(E) dated 7/12/94.
90	Amendment to Rule 150 (E) (g)	-	Final notification published vide GSR 93(E) dated 24/2/95.
91	Consideration of changing the definition of 'qualified person' under rule 65 (15) (c) (ii) 'Regd. Pharmacist' so as to be as par with Pharmacy Act 1948.	-	Final notification published vide GSR 676(E) dated 6/9/94.