MINUTES OF THE 33rd MEETING OF THE DRUGS CONSULTATIVE COMMITTEE HELD ON 30th & 31st AUGUST, 2000

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The agenda items were thereafter, taken up for discussion.

A. Confirmation of the minutes of the 32nd DCC meeting held on 22nd and 23rd September, 1998.

The members confirmed the Minutes.

B. I. Consideration of the action taken report based on agenda related to the 31st DCC meeting.

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

After discussion, it was decided that proposal needs to be re-examined by the same sub-committee under the Chairmanship of the Commissioner, FDCA, Gujarat.

The members suggested that few State Drugs Controllers who showed keen interest in resolving this issue may be co-opted as members.

The committee needs to also examine the likely implications of restricting the number of licensees through proposed regulatory provisions and the modalities which would have to be followed by the licensing authorities. Possibly, the views of trade associations and some consumer organizations may also be brought out in the final report of the committee.

Item No. 2 : Proposal regarding monitoring on quality / efficacy of the biological products (human / veterinary) including veterinary drugs.

While considering the proposed fees structure, it was decided that the Director, IVRI, Izatnagar (U.P.) shall review the proposed fees structure of each category of Drugs along with the reasons for justifying the proposed fee to be charged from the Indian manufacturers / Importers.

The Director, IVRI, agreed to furnish a write-up in this regard within 30 days.

B. II. Consideration of the action taken report based on agenda related to the 32nd DCC meeting.

Item No. 2 : Deletion of clause (a) from the Provisions of Chapter IV under "Extent and conditions of exemption" Sl. No.13 of Drugs and Cosmetics Rules (Household remedies).

The DCC sub committee's report dealing with various issues concerning OTC drugs, household remedies etc. was introduced by committee's member secretary Shri Anandrajshekhar and was extensively discussed.

The recommendations of the committee, as specified under para 17 of the report, were endorsed by the members.

The Chairman requested the members to convey further opinion / suggestions, if any, within a month after which the recommendation may be processed for necessary follow up action.

Item No. 4 : To change the designation from 'Inspectors' to a suitable designation befitting importance of their role to perform the work under the Drugs & Cosmetics Act and Rules thereunder.

The Committee requested the Commissioner, FDA, Gujarat to get the matter examined through Expert Standing Committee as per the earlier decision taken and submit its recommendation at the earliest.

Item No. 18 : Consideration for the amendment of Rule 85(2), so that powers to the licensing authority cannot be challenged by the appellate authority or the court.

As the members could not go through the report submitted by the Expert Standing Committee as the same was not available on 30.8.2000, the Chairman suggested that the members should forward their comments within one-month time.

Item No. 24 : Consideration of the questions whether Sanitary Pad be classified as 'drugs'.

Many of the members stated that they have already started issue of manufacturing licence for sanitary pad as a 'drug'. Since, it has been already directed by Hon'ble High Court, Mumbai that 'Sanitary Pad' is to be classified as 'drug', the members suggested that steps may be taken to classify Sanitary Pad as a 'drug' under Drugs and Cosmetics Rules.

Necessary amendments in this regard in Drugs and Cosmetics Act and Rules thereunder is to be considered.

Supplementary agenda items of 32nd DCC Meeting dated 22nd / 23rd September 1998.

Item No. 1 : Consideration of extension of shelf life of Rifampicin capsules in Schedule 'P' in Drugs and Cosmetics Rule and modification of packaging of Ethambutol tablets.

So far as the consideration of shelf-life extension of Rifampicin capsule is concerned, the Chairman requested the Director, CIPL, Ghaziabad, to expedite the stability studies of Rifampicin capsules of reputed brands available in the market.

The committee recommended that after receiving the said stability report from the Director, CIPL, Ghaziabad, DCG(I) may decide the matter.

Item No.3.2 : Consideration of the proposal for introducing new sections in the Drugs and Cosmetics Act for offences committed by an approved testing laboratory.

The Chairman requested the Drugs Controller (Delhi) to forward a draft proposal justifying the need for incorporation of penalty clause at appropriate place in the Act for offences or contraventions committed by approved testing laboratories.

Item No.7.1 : Proposal to make amendment in Rule 148(1)(b) related to the manner of labeling of cosmetic products.

The Committee was informed that the draft nofitication on subject proposal has already been published and sent to State Licensing Authorities and other stake-holders for comments.

Item No.7.2 : Consideration to make amendment in Section 25(4) of Drugs and Cosmetics Act, pertaining to the report of the Govt. Analyst and some changes in Forms 27, 28, 27-A, 28-A, 27-F, 28-F, 28-D, 27-D and in rules 27, 75(A), 76, 79(A), 65(2) and 66 of the Drugs and Cosmetics Rules.

The members could not go through the report submitted by the Expert Standing Committee on 30.8.2000.

The Chairman suggested that the members should forward their comments within one month time. Thereafter, follow up action would be intiated by the office.

B. III. Consideration of the action taken report on the minutes of special Drugs Consultative Committee held on 26th July 1999, on the recommendations made by Hon'ble NHRC vide its Order dated 31.3.99.

iii) **To ensure GMP inspection of manufacturer's premises at least twice a year by competent trained persons, and introduce a GMP Certificaiton Scheme for domestic manufacture in line with WHO GMP Certification Scheme, and after each inspection the Inspector record comments on compliance of GMPs in a register specially maintained at the manufacturer's location.**

The Chairman intimated that the GMP Audit Training Programmes for the State Regulatory Officers under WHO assistance are under process.

He recalled that in the special meeting of DCC, the members were requested to identify specific areas on which training modules need to be developed and faculty be identified.

It was also discussed that every State should have a core staff to undertake GMP / GLP audits so that there is uniformity and continuity in regulatory modalities.

As regards to the uniformity of the formats for GMP, non-conviction, free sale performance etc., a group of State Drugs Controllers has already designated uniform proforma, which have been received on 30.8.2000.

Since, the members could not go through the report due to paucity of time, the Chairman suggested that the members should forward their comments within one month time.

xii) **To ensure that all hospital stores are audited and inspected by the Drug Control Administration as per the statutory requirements at least once in a year.**

The proposed checklist prepared by the Expert Committee had been circulated along with the 33rd DCC agenda papers.

The members stated that they will forward their comments after examination of the proposed checklist within one month time.

33rd Drugs Consultative Committee Central Agenda Items :

Item No.1 : Regulatory Control on Medical Devices.

The members after deliberations decided that various medical devices presently used in the healthcare system, in addition to those notified, are to be identified for their standards to be classified in Schedule R-1 under Drugs and Cosmetics Rules. This would facilitate better regulatory control of wider range of medical devices.

A sub-committee with the following members under the Chairmanship of FDA, Maharashtra, shall examine the issue :

1.	The Commissioner, FDA, Maharashtra	-	Chairman
2.	The Commissioner, FDCA, Gujarat	-	Member
3.	The Drugs Controller, Haryana	-	Member
4.	The Drugs Controller, Karnataka	-	Member
5.	The Drugs Controller, Delhi	-	Member
6.	The Dy. Drugs Controller (I), W.Z.	-Member Secretary	

The members also suggested to include a representative from the BIS in the said Sub-Committee.

Item No. 2 : Recycle of used disposable needles and syringes in healthcare system.

The DCG(I) introduced the agenda and acquainted the members with the general apprehension in public mind about wide spread reuse.

The members from some States viz. A.P., West Bengal, Karnataka and Kerala agreed that instances about reuse of single use disposable syringes and needles in hospitals are noticed. Many of the members stated that due to economic constraints some State Govt. Hospitals reuse disposable syringes and needles after proper sterilization. Many of the members stated that rag-pickers used to collect thrown away plastic syringes due to the high quality of the plastic used in it, but re-cycling of such materials for circulation in market was not in their experience. Such thrown away

plastic might be used for making other plastic products and by itself did not pose any health care problem.

The members proposed that since the issue was not alarming, as being projected, no specific measure was required to be taken at the present moment.

Based on the deliberations made, the Chairman requested all the State Drugs Controllers to submit a status report pertaining to the issue as many Hon'ble Members of Parliament have also drawn the attention of the Govt. regarding the alleged sale of recycled disposable syringes. The factual position thereof needs to be clearly explained by all State Drugs Controllers.

Item No. 3 : Consideration of use of medical oxygen from various sources and possible regulatory control of the same.

Details regarding production and supply of Oxygen gas 93% to hospital patients in various countries from dedicated hospital based plants was explained to consider whether the production of Medical Oxygen in Govt. hospitals and Institutions need to be accorded Schedule K exemption under the provisions of the Drugs and Cosmetics Rules.

The members, after deliberations, decided that since Oxygen 93% had already been specified in U.S.P., such Oxygen produced by any hospital plant might be labeled as Oxygen 93% U.S.P. However, before issuing blanket permission for the use of Oxygen 93% under I.P., opinion about its safety and efficacy might be obtained from leading anaesthesists.

The Drugs Controller, Delhi Administration was requested to coordinate with various hospital authorities in Delhi and suggest suitable policy.

The members agreed, in general, for Schedule K exemption for the captive production of Oxygen in Govt. hospitals to be used for hospital patients under prescribed conditions.

Item No. 4 : Consideration for the regulatory control of Oxytocin Injection B.P.Veterinary to prevent the indiscriminate use of the drug in veterinary practice.

Members were informed about the intensity of issue and to give their suggestions to curb the indiscriminate use of Oxytocin Injection in Veterinary practices.

The members were unanimously of the view that Oxytocin Injection could not be banned due to its effective therapeutic role, but regulatory measures

may be made more stringent to discourage unwarranted manufacture and distribution of this drug.

After long discussions in the matter, the members suggested that the raw material manufacturer of Oxytocin bulk should sell the drug to the actual users (Formulators) only and the production and distribution of Oxytocin Injection should be monitored periodically by the State Regulatory Authorities.

It was also recommended that the manufacture of Oxytocin Injection be restricted to a single dose blister pack. Necessary changes in the Drugs and Cosmetics Rules may be initiated for this purpose.

Item No. 5 : Matters arising out of deliberation held at the All India Conference of State Drugs Administration organized by NPPA on 26.4.2000.

The agenda was kept in the 33rd D.C.C. meeting to review some of the regulatory issues discussed in the meeting on 26.4.2000.

5.1 : Common software for State Drugs Control Organisation, Deptt. of Health and NPPA (Item No.8 of the minutes circulated by NPPA).

The members felt that the needs of the State Drugs Control Administrations were vastly different from those of the NPPA and a separate dedicated software was needed by the States to computerize their operations.

At this point, the DCG(I) informed that an expert has already been identified and appointed as WHO Consultant, who was in the process of making a feasibility study to computerize and network operations of the State Drugs Control Organisations as well as the CDSCO. An interim report has already been prepared in the matter and the process would be initiated within this financial year.

The consultant Shri Brijesh Regal gave a detailed presentation on the proposed project. It was informed that –

A) Under the Centrally sponsored finance scheme, necessary hardware as well as software will be provided by the CDSCO.

B) The software will be highly sophisticated and extremely easy to operate. It will be entirely menu driven.

C) Sufficient training will be imparted to the State officials.

D) A coordination committee of State Drugs Control would supervise the data entry and software development.

E) Funds would be provided to enable data entry through external support at all State offices.

F) Attempt would be made to introduce on-line licensing.

The members of DCC appreciated initiative being taken by Centre and hoped that after its completion this may bring a paradigm shift in the drugs regulatory environment in the country.

5.2 : Branding of drugs as 'Ayurvedic' to escape price control (Item No. 11 of the minutes circulated by the NPPA).

The D.C.C. members opined that such practices are not necessarily for any price benefits. The manufacturers enjoyed the advantage as Ayurvedic drugs, need not be sold through licensed sales outlets.

Since, the issue has been raised by NPPA, the members felt that they would closely examine it and convey their views.

Drugs Controller, Karnataka and Commissioner, FDA, Maharashtra agreed to examine the issue.

5.3 : Steps taken for identification and elimination of spurious drugs (Item No.13 of the minutes circulated by NPPA).

Members were briefed by DCG(I) about the seriousness of the issue and initiatives taken by CDSCO in framing appropriate modalities for States to follow and to encourage participative efforts from drug industry and trade. Extensive survey sampling and speedy analysis are critical parameters.

All the members, during discussions, showed their concern about the menace of spurious drugs.

The members from several States expressed their views about the difficulties faced by them in respect of getting information and cooperaton from their neighbouring States. Members from Karnataka, Andhra Pradesh & Maharashtra specifically indicated that they could not get any specific information from the State Drugs Controller, U.P. The representatives from U.P. Drug Control Deptt. intimated that such type of queries from other States did not come to his direct knowledge and as a result he could not initiate appropriate action in this regard. He assured that all possible assistance would be provided in the future. In his statement, the member from U.P. stated that they had serious problem for

testing of drugs samples drawn by the Drugs Inspectors. Only 20% samples get tested in the Central Drugs Laboratory, Calcutta, others simply get expired while in the queue for analysis. He, therefore, sought help for testing of drugs samples drawn by the Drugs Inspectors. As per his statement, U.P. had identified 59 spurious drug samples in the current year.

The Chairman advised the State Drugs Controller that in the matter of spurious drug, one does not have to depend upon routine correspondence. Speedy information exchange is essential. There need to be one to one interactions between concerned authorities to expedite follow up measures.

The Drugs Controller, Rajasthan also expressed similar difficulty.

After long deliberations in the matter, DCG(I) emphasized that direct interaction between concerned State officials is critical in case their written requests were not responded to. All the members agreed to the suggestions made by the DCG(I).

It was agreed that periodic zonal level meetings should be held jointly with the representative of IDMA, OPPI and AIOCD.

It was also suggested that at the zonal level meeting case studies may be made of spurious / counterfeit drugs unearthed.

5.4 : Measures for promoting identification of obsolescent drugs (Item No. 14 of the minutes circulated by NPPA).

In the NPPA Meeting, a view was taken to investigate the reasons for declining production of low priced drugs which were popular with the consumers. The State Drugs Controllers were requested to check up the issue and to identify the reasons thereof.

The matter was deliberated in length and it was decided that the Drugs Controller, Karnataka would make a study in this regard and circulate to all the members for comments. The DCG(I) suggested that a copy of the finding should also be forwarded to NPPA. The issue relates to prescription practices, economy of production, availability of newer drugs etc.

Item No. 6 : Consideration for prescribing standards for diagnostic kits and reagents, and separate schedule for prescribing plant and machinery required for manufacture of such kits and reagents.

The committee strongly recommended the need for making necessary provisions in the Drugs and Cosmetics Rules in respect of the 'classification' and 'standards' of various diagnostic kits and reagents and to prescribe a separate Schedule for Plant and Machinery required for the manufacture of such diagnostic kits and reagents.

It was agreed to constitute a sub-committee with the following members to study the matter and suggest necessary measures:

1) Commissioner, FDA, Maharashtra	-	Chairman
2) The State D.C., Goa	-	Member
3) Commissioner FDCA, Gujarat	-	Member
4) D.C., Karnataka	-	Member
5) Director, NIB	-	Member
6) The State D.C., Delhi	-	Member
7) Shri S.P.Das, DDC(I)	-	Member Secretary

The sub-committee may also co-opt a member from AIIMS and DBT.

Dr. Rajesh Bhatia, Director NIB was then invited to brief the members of DCC about the institute and its long term perspectives. He also informed the members that the institute is expected to be soon ready to work as statutory laboratory for testing of biological products, including blood products and diagnostics.

Item No. 7 : Revision of Schedule to the Drugs and Magic Remedies (Objectionable Advertisement) Act.

Members expressed concern about advertisement for cure of diseases like AIDS. In this matter the Chairman intimated that a sub-committee has already recommended various changes in the DMR(OA) Act.

After deliberations, the members suggested that necessary steps may be taken as per the recommendations made by the sub-committee under the Chairmanship of Dr. Ranjit Roy Chowdhury.

However, in the meantime under the rules of DMR(OA) Act, AIDS may be added as a disease / disorder for which advertisement of a 'drug' should be prohibited.

Item No. 8 : Consideration for the availability of Morphine tablets for cancer patients.

The Agenda was kept to discuss the *modus operandi* adopted by various State Drugs Controllers to ensure the availability of Morphine tablets of

cancer patients in the light of modified policies made in NDPS rules and revised excise rules in the States.

The exemption provision to the 'Pain and Palliative Care Centres' under Schedule K has already been approved by the DTAB and placed for incorporation in Schedule K. The State Drugs Controllers shall now approve them and evolve suitable procedure for approval or licence to them.

Some of the State Drugs Controllers, Orissa, Goa, Kerala intimated that they have already made such procedure in this regard and they would send the details of the same to DCG(I) to apprise the same and to facilitate other States to make such procedures.

Item No. 9 : Consideration for the licensing of Blood Storage Centre.

This agenda was kept in pursuance to the recommendation of the National Blood Transfusion Council that various hospitals and Primary Health Centres which are not in a position to provide all the requisite facilities for a Blood Bank, may operate Blood Storage Centres under Drugs and Cosmetics Rules with some restricted conditions.

The members agreed with the recommendations made by the NBTC and suggested that a suitable proposal in this regard may be placed before DTAB for inclusion of necessary provision in the Drugs & Cosmetics Rules.

Supplementary Agenda

1. Consideration of issue of whole human blood and its components to the hospitals without cross matching.

Consideration for licensing of Blood Storage Centres action taken & recommendations :

Mr. R. Narayanaswamy (CDSCO) made a brief presentation on the subject and recommended that storage of blood should be allowed only in government hospitals. He suggested that storage of blood components should also be allowed in hospitals and they should be licensed for the purpose. He felt that the quality of the blood stored would not get tracked if the hospitals were not licensed and made to follow the rules.

Mr. Tripathi (Goa) suggested that each storage facility should be attached to a specific blood bank so that its supplies can be tracked down to the relevant blood bank.

On the contrary Dr. Bagchi (West Bengal) felt that storage of blood should be exempted under Schedule K, but other members disagreed with this suggestion.

DC, Karnataka felt that the suggested criteria of 200 sq. feet should be altered to state "an adequate area".

States were asked to submit their comments on the proposals within 30 days after discussing with their colleagues.

2. **Grant of exemption to the First Aid Kit to be supplied along with the delivery of motor vehicle by the manufacturer mandatory under the Motor Vehicles Act.**

After deliberation, the members agreed that the First Aid Kit supplied by the manufacturers of motor vehicle should be exempted under Schedule K from the provision of sale licence under Drugs and Cosmetics Rules, subject to the condition that the respective drug items of the kit shall be procured / purchased from a licensed manufacturer / dealer of the drugs.

3. **Consideration of the proposal to amend Rule 51(1) and 52(1) related to duties of Inspector.**

The agenda was placed on the basis of request from the Minstry of Health that duties of Inspector might be reviewed in respect of minimum requirements for the inspection of manufacture and sale premises for not less than twice a year.

Chairman explained that it is felt that in the overall context of drug regulatory procedures and the objectives of legal framework, specifying requirement of twice a year inspection presently, does not appear to be necessary. The frequency of inspection may be reasonable and may also be related to availability of enforcement personnel as well as the status of licences. The quality of inspection and self-regulatory mode by the licensees need to be encouraged.

Some of the members were of the view that their present manpower planning is based on the existing statutory provisions.

After discussion, members suggested that proposal may also be referred to DTAB for consideration.

4. **Consideration of the proposal to include as one of the conditions of licences for manufacture of drugs for furnishing two copies of consolidated price list in Form V of DPCO.**

This proposal was kept on the basis of request received from Deptt. of Chemical & Petrochemical that licensee (manufacturer) might be asked to comply with the provisions of DPCO and submit two copies of price list to the SLA to monitor the price of the formulations as fixed by NPPA.

The members after deliberations, opined that considering the shortage of inspectorate staff, it would not be possible to monitor the price aspects of drugs in general and the proposed amendments may have implication.

The Chairman, however, advised that licensees may be directed to file a copy of price list while applying for renewal or product approval etc.

33rd DCC State Agenda Items:

ASSAM

Item No. 10 : Consideration of upgradation of State Drugs Testing Laboratory, Khanapara, Guwahati to full fledged regional drug testing laboratory for North Eastern region.

Drugs Controller, Assam explained that the State Drug Testing Laboratory, Assam may be upgraded to establish it as a Central Drugs Testing Laboratory for the North East Region.

The members agreed with the proposal made by the Drugs Controller, Assam. There is a need to have a well equipped and viable drug testing lab to cater to the needs of N.E.States.

The DCG(I) intimated that the said lab has already been taken over by the Central Government and necessary formalities are in progress. With this Central lab coming up, objective of N.E. States would be fulfilled.

ANDHRA PRADESH

Item No. 11 : Consideration of framing guidelines to serve summons to the accused in the other States.

Mrs. Janki Reddy, Drugs Controller, Andhra Pradesh, described the problems that her officers face when they have to serve summons to the accused in other States. She stated that some States do not furnish the information about the licensees inspite of several reminders.

Chairman emphasized that names of the licensees should be sought only after proper investigations have been completed.

It was also advised to the members to personally speak to the concerned State Drugs Controllers if they face any difficulty.

Item No. 12 : Consideration to follow uniform procedure while permitting manufacturing approval of new combinations.

DCG(I) explained, in detail the alround criticism about plethora of drug combination's and the role of some State Licensing Authority in deviation to the legal requirements. This had resulted in Govt. of India having to intervene by issuing direction under Section 33P to all State Govts.

All the members expressed serious concern about the non-uniformity in the implementation of laws while granting licences for new drug formulations by some States.

FDA, Maharashtra, suggested that no State should henceforth grant any licence for a New Drug Combination and should refer the application to CDSCO. The CDSCO should then process the application in a time bound manner.

Some members, during discussions, felt that there should not be any requirement to submit further application for approval, once a drug had already been approved by the DCG(I).

The members also felt that 4 years time frame for a new drug may be reviewed. The DCG(I) explained the background about why four years time period was introduced. Generating adequate data on safety, efficacy etc. needs reasonable time and proper follow up.

DCG(I) also felt that many of the fixed dose combinations were fit cases for re-examination. He intimated that existing quarterly information of New Drug to the State Authorities would be continued. He further strictly directed the members not to licence any new drug.

The DCG(I) also cautioned that in case of approval of any new drug in future by any member state, the matter would be directly reported to the Govt. of the concerned state, and this may put concerned licensing authorities in a difficult situation.

Item No. 13 : Consideration to allow trade name assigned by some manufacturers.

a) The issue of some brand owners allowing more than one manufacturer to produce the products under that brand was discussed at length.

Mr. Gudal, (Maharashtra) said that the issue involved capacity constraints with any one manufacturing unit. He suggested that the manufacturer may

be asked to write on the pack the name of the owner of the brand. It was informed that an overseas product may be distributed under different brand names in India and in other importing countries.

FDA, Maharashtra was requested to seek legal opinion in the matter.

b) Mr. Gudal, Maharashtra and Mr. Jain, Haryana said that they were granting licences for more than one brand name for the same drug to one manufacturer. They felt that this helped the industries in general and small scale industries in particular in utilizing their spare capacities.

The Chairman stated that such practice requires that care is taken to monitor all the brands together in case of sample of one of the brands fails in analysis. In such a scenario, it may be considered if all the licences granted for various brand names of a particular product need to be revoked / cancelled or suspended together.

c) Members cited several examples where the same brand name was being used by different companies for different products.

While they agreed that it could cause serious medical complications if an unintended drug got dispensed – they agreed that in the absence of a consolidated list of the brand names already approved – there is nothing they could do to help the matter. In any case, this could be violation of Trade and Merchandise Marks Act and not of any drugs laws.

Mr. Brijesh Regal (WHO Consultant) informed the committee that with the computerization of States and CDSCO operations – such as complete list of brand names will form the backbone of networking system and then the problem will resolve itself.

However, the members were advised to strictly ensure that closely resembling name (brand) are not permitted for same product or different drug.

Item No. 14 : Consideration for the amendment to the concerned Rules under Drugs & Cosmetics Rules 1945 to make provision for the manufacturing of LVPs under loan licence.

The issue was discussed in the light of the fact that in the absence of clear provision under CLAA dispensation, the manufacture of Metronidazole Inj., Ciprofloxacin Inj. etc. in 100 ml bottles continues under earlier system of loan licence in some States. Some members felt that licence for such specific LVP products may be regulated under Form 28A. The restriction may only be on conventional I.V. Fluids.

The members after deliberations in the matter decided that a Committee be constituted with the following members to look into the matter.

1. Commissioner, F.D.A, Maharashtra	-	Chairman
2. State D.C., Karnataka	-	Member
3. Commissioner FDCA, Gujarat	-	Member
4. DDC(I), WZ	-	Member Secy.

The Director of Drugs Control, West Bengal who wanted to make some suggestions in the matter was advised to forward his comments directly to the Commissioner, FDCA, Gujarat.

The committee should submit its report withing three months after examining the (i) existing practices (ii) legal provisions (iii) nature of products (iv) policy, amendments needed etc.

DELHI

Item No. 15 : To consider amendment of Schedule K to insert new provisions in the conditions of exemption under Sl. No. 5(a) and Sl. No.13.

The members agreed that the Rules should specifically indicate that Hospitals should purchase drugs only from a dealer or a manufacturer licensed under the Rules.

The amendment proposed by DC, Delhi was accepted.

GOA

Item No. 16 : Consideration of the proposal to amend Schedule Q of the Drugs and Cosmetics Rules to bring it on line with IS:4707 Part I.

The issue was discussed in detail and the members suggested that the matter should be taken up with BIS so that Schedule Q of the Drugs and Cosmetics Rules may be updated to bring it on line with IS:4707 Part I.

Item No. 17 : Consideration of the question as to whether the products which are manufactured for export under Neutral Code under the provisions of Rule 94, can be permitted to mention the name of the firm, located abroad, whose identity is not known.

(i) Mr. Gudal explained that it was the overseas buyer who desired to have his / another person's name to be printed on the labels of the drugs being exported from the country.

Members agreed that such a practice may be allowed / continued for export purposes.

(ii) Members from Orissa informed that diagnostic kits are being imported in bulk packs and then being repacked without any licence.

The member was advised to inform the committee about such units / importers or resellers.

(iii) Mr. Tripathi, (Goa) informed that some companies were importing tablets in bulk packing, re-packing them in unit pack in India and then re-exporting the products.

Since these units had the relevant manufacturing licences, there was nothing wrong with the practice.

Item No. 18 : Consideration of the proposal to make suitable amendment under Clauses (b) of sub Rule (1) of Rule 148 of the Drugs and Cosmetics Rules, at part with Clauses (iv) of sub rule (1) of Rule 96 of the Drugs and Cosmetics Rules.

The Chairman intimated the members that the directions have already been issued to the effect that the cosmetic manufacturer must write their complete address along with the pin code on the label of their products.

Item No. 19 : Consideration of the question for the manufacture of tooth paste under cosmetic manufacturing licence, by making claim as herbal tooth paste.

The issue regarding the manufacture of herbal tooth paste under cosmetic manufacturing licence was discussed in detail.

Majority of the members found nothing objectionable in writing the word "herbal" on the pack of a tooth paste as long as it contained herbal extracts. The products would have to conform to BIS specification.

However, the Chairman suggested that the issue should be examined in detail. The D.C., Goa has been entrusted to make a proposal in detail for further examination.

Item No. 20 : Consideration for prescribing uniform limit regarding net content of liquid oral forms.

The subject issue in relation to the I.P. limits and provisions under Schedule V was discussed in the meeting.

It was decided that Director, CIPL, would study the issues and suggest corrective measures.

GUJARAT

Item No. 21 : Consideration for including standards for certain pharmaceutical products.

The related issues were discussed and the members suggested that :

(A) Need for inclusion of Pyrogen Testing in BIS Standards for disposable syringes is to be brought to the knowledge of the concerned BIS authorities.

(B) & (C) Both the issues in respect of standard for rubbed and dotted condoms, and limits of preservatives for ophthalmic preparations respectively are to be referred to the Director, CIPL for necessary examination.

HIMACHAL PRADESH

Item No. 22 : Consideration for the condition to be satisfied under Rule 64 for licences in Form 20, 20B, 20F, 20G, 21, 21B for grant or renewal.

The subject issue was discussed in the meeting and it was decided that no further action is required presently. Concept of wholesale dealing is much different than retail sale (Community Pharmacy).

KARNATAKA

Item No. 23 : Consideration for laying down standards for new bulk drugs.

The subject issue was discussed in detail and it was decided that CDSCO and State Licensing Authorities will ask the applicant to submit the standard sample along with the application. The samples will then be tested by CDL / CDTL as per the protocol provided by the applicant. A portion of the sample will then be retained by CDL / CDTL as reference standard for future analysis.

Item No. 24 : Proposal for clarification of Rule 150-B(2) in respect of submission of application in Form 36 and payment of fees.

The Chairman clarified that issue was being taken care of while a new schedule of licence fee was being drafted.

Item No. 25 : Proposal to clarify on the Government approved laboratory for analysis of certain biological drugs.

The Chairman informed the members that National Institute of Biologicals, Noida, UP is likely to be notified under Rule 3 for the purpose of testing biological products viz. Blood Products, vaccines and diagnostics.

Drugs Controller, Karnataka was advised to draft a protocol for drawing samples of Blood.

Item No. 26 : Consideration of the proposal of dealing in drugs through Internet.

Members felt that the issue is not relevant in the present scenario. The Chairman invited Mr. Brijesh Regal (WHO Consultant) to give his opinion on the issue.

Mr. Brijesh Regal stated that even in the present scenario the retail chemists were home delivering the medicines and Internet pharmacies will definitely become a reality in very near future. He informed the members that Royal Pharmaceutical Society of Great Britain has drafted some guidelines on the issue. Chairman asked Mr. Brijesh Regal to compile such guidelilnes / legislation prepared by overseas bodies and present them to the Committee which would help in forming suitable policy.

Item No. 27 : Consideration of the study of the test protocols by the Central Drugs Laboratory, Calcutta while testing the sample of P&P medicines.

The Director, CDL stated that testing methods given by several manufacturers were often found to be non-validated. In such cases, other validated methods were used to test the samples.

He stated that in several cases they informed the manufacturers about such inconsistent methods of analysis forwarded by them. He also explained about the situation when the testing methods given by manufacturers can not be accepted.

Mr. Anandrajshekhar, Drugs Controller, Karnataka, was advised to seek further clarifications directly from the Director, CDL, Calcutta.

Item No. 28 : Consideration for amendment of certain provisions under Drugs & Cosmetics Rules, 1945 to facilitate implementation of the regulatory norms.

Both the issues relating to the amendment in Sl.No.15 of Schedule K and Rule 52 of D&C Rules had been accepted by the members and suggested for the approval of DTAB.

KERALA

Item No. 29 :Consideration for the categorization of minor offences under the Drugs & Cosmetics Act and providing for compounding of offences.

The recommendations of the sub committee were accepted. The Chairman requested the members to further give their specific views, if any, within 30 days.

It was agreed that the recommendations may be implemented. The proposal was accepted in principle.

Mr. Venkatakrishnan, Drugs Controller, (Kerala) was asked to give a preamble of the issue along with clear recommendations, citing other statutes where such provisions were available. Other States were advised to facilitate the matter by giving their suggestions and inputs to Mr. Venkatakrishnan. Earlier directions given by the Government in this regard were also sought to be included in the preamble.

Item No. 30 : Need for relaxation in the amended provisions of the Drugs & Cosmetics rules applicable to Blood Banks.

Members agreed with the proposal in principle.

It was stated by D.C. (Kerala) that the Government doctors get frequently transferred, and re-notifying a new person is a lengthy process. The blood bank operations could not be stopped while the Government procedures were being completed.

Members felt that the problem is being realized after the law has come into force.

It was suggested that a sub-committee with following members would examine the issue and similar such issues and make recommendations within 30 days. The deliberation of committee may also be conducted through e-mail or circulation of views etc.

1) D.C., Kerala - Chairman

2)	FDCA, Gujarat	-	Member
3)	FDA, Tripura	-	Member
4)	FDA, Sikkim	-	Member
5)	D.C., Karnataka	-	Member Secy.

Item No. 31 : Matter pertaining to objectionable advertisements.

Members suggested that the issues referred would be taken care of as decided under Agenda Item No.7.

Item No. 32 : Consideration for the issue of WHO GMP Certificate.

Decision was taken in the meeting that since issuing a WHO GMP certificate is not a statutory tasks, States were advised to frame their own rules about charging the fees.

Commissioner, FDCA (Gujarat) informed that they were charging Rs.1000 for each WHO GMP Certificate and Rs.50 for each additional copy.

He was advised to send a copy of their fee structure and other guidelines to other States to help them prepare their own rules in this regard.

MAHARASHTRA

Item No. 33 : Consideration of amendment to entry 5(a) of Schedule K of the Drugs and Cosmetics Rules, 1945.

Chairman iformed the members that the issue has already been resolved.

Item No. 34 : Consideration of the conditions under which exemption is granted to registered medical practitioners (RMPs) under Schedule K.

The agenda was withdrawn by FDA, Maharashtra.

Item No. 35 : Consideration for uniformity in maintenance of manufacturing records by soap manufacturers.

The matter was discussed in length.

The members suggested for uniformity in maintaining the records and for effective implementation, it is necessary that the proviso to Rule 142 may be deleted.

Item No. 36 : Preparation of comprehensive guidelines for granting permission to manufacture drug formulations for export purposes.

Chairman informed the members that needful was being done under directions from the Hon'ble Supreme Court. The conditions have been approved by the Ministry of Law.

ORISSA

Item No. 37 : Consideration for the modalities to be adopted for suspension / cancellation of blood bank / LVPs licences.

The issue of joint inspection by CLAA and SLA was discussed extensively by the members.

Many members were of the view that CDSCO should also directly use the instrument of cancellation if the situation so warranted. Members felt that the whole issue of joint inspections / licensing by CLAA and SLA should be done in a lawful manner. The CLAA should also takes responsibility for suspension / cancellation of licence.

It was pointed out that the licence Form at one place stated, "delete whichever is unnecessary" which could be interpreted in such a way that only one of the two (CLAA or SLA) could sign the inspection report.

Members felt that the whole issue of joint inspections / licensing by CLAA and SLA needs to be reconsidered in the light of new experiences obtained.

Item No. 38 : Consideration to amend the existing Forms 20A and 21A of the rules to draw a specific list of category of drugs those can be catered under those licences uniformly throughout the country.

The committee agreed for a uniform list for the purpose.

Members from Delhi and Orissa were asked to send the list prepared in their States for consideration of CDSCO so that a uniform list could be arrived at.

Members agreed that the provision relating to purchase of medicines from specified dealers only should be removed.

Necessary amendment in Drugs and Cosmetics Rules was recommended.

Item No. 38-A: Limit of bacterial Endotoxin units in LAL test.

The issue regarding the limit of Endotoxin units in LAL test was referred to the Director, CDL with the advise to send his comments directly to D.C., Orissa.

RAJASTHAN

Item No. 39 : Time bound policy for providing the constitution of manufacturer & details of manufacturing chemist & analytical chemist.

The issue was discussed in the meeting and the members suggested that necessary guidelines as mentioned under Agenda Item No. 5.3 will be followed in this case also.

TAMILNADU

Item No. 40 : Consideration to print the name of the printer on the label of the drug / aluminum foil etc.

The members felt that the proposal is not feasible and hence not to be considered.

WEST BENGAL

Item No. 41 : Consideration for deliberation of certain regulatory proposals for better clarification.

The issues relating to the agenda were discussed.

The measures recommended by the members are as follows :-

41.1 Legal status of test reports issued by the Govt. testing laboratories, not in Form 13 and by approved laboratories.

Test reports issued by Government approved private testing laboratories have no statutory standings.

41.2 Status of sale licence or manufacturing licence after the death of the proprietor in case of a proprietorship firm and to clarify whether his legal heirs can apply for a subsequent licence to consider as a licence due to change in constitution.

The Commissioner, FDCA, Gujarat was requested to provide relevant clarification in the matter for information to all other States.

41.3 : **Dextropropoxyphen, Ephedrine Hydrochloride, Amphetamine, Buprenorphine Hydrochloride should come under Schedule X licence.**

After detailed discussion on individual products including the extent of their production and use etc., the members agreed with the suggestion that Buprenorphine Hcl should be brought under Schedule 'X'.

However, opinon of few renowned clinicians experienced in using this drug may also be obtained.

41.4 : **Common formats for licence validity certificate.**

No conviction certificate, No prosecution certificate, Free sale certificate, Market standing certificate, Performance certificate, GMP certificate (WHO and Non WHO), Capacity verification certificate, Narcotic utilization certificate.

The Chairman intimated that the D.C., (A.P.) is already working on the preparation of the common formats for various Licence Validity Certificates as desired by the Director, Drugs Control, West Bengal.

The meeting ended with vote of thanks to the Chair.

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Annexure – I
(Item no. 2 of the 33rd meeting)

Statement showing the action taken on the decisions taken at the 32nd Meeting of the Drugs Consultative Committee held in New Delhi on the 22nd & 23rd September 1998.

NO.	SUBJECT DISCUSSED	DECISION TAKEN	ACTION TAKEN
(1)	(2)	(3)	(4)
1.	Consideration of the proposal to amend Rule 64 so as to	The sub-committee report was taken for discussion. A large number of the	Based on the decision taken, the report of the subcommittee on the proposal was

	prohibit or restrict excessive concentration of Chemists Shops at a particular location.	members, specially the Commissioner, FDA, Maharashtra, felt that many of the recommendations of the sub-committee are very rigid. He specifically desired that so far as ownership is concerned, it should be open to all concerned to start and run any retail or wholesale premises. Considering the total aspect of the sub-committee report, the Chairman requested that the Agenda should be re-examined by the sub-committee and recommendations should be forwarded along with the comments from the Chemists and Druggists Association.	referred to the Commissioner FDCA Gujarat for reviewing. It has now been informed by the Commissioner FDCA Gujarat that the report of subcommittee is in order and required no further changes. Members may like to take final view in the matter.
2.	Proposal regarding monitoring on quality / efficacy of the Biological products (Human / Veterinary) including veterinary drugs.	The members discussed the matter with the Head of the Standardisation Division of IVRI. DDC(I), West Zone, was requested to provide a list of vaccines which may be required to be tested at IVRI. ADC(I), IGIA, Delhi desired to know the mode and approach to be followed to send the vaccine samples to IVRI. The IVRI representative said that testing can only be possible if the testing fees are re-imbursed by the agencies	A revised fees structure in respect of Veterinary biological has been proposed by IVRI. The members may examine the proposal.

		desirous for such testing. The Chairman requested the IVRI to examine the fees structure to be levied by them in the light of the provisions given under Schedule 'B' of Drugs and Cosmetics Rules. Finally, the members recommended that a complete write-up from IVRI on the subject may be obtained on the points discussed above.	
3.	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 impugned samples of drugs by the manufacturer and sales outlets.	The members discussed the matter in the light of the recommendations made by the 45th DRUGS TECHNICAL ADVISORY BOARD. The matter was discussed from various angles like shortest possible time for effective recall, fool-proof mechanism to freeze the sale and manufacture of the impunged drugs, etc. However, the members felt that it is very difficult to incorporate any statutory provisions in the Drugs and Cosmetics Rules relating to the time-bound recall of the drugs at the present moment.	Decided not to amend the Rules immediately. Guideline for expeditious recall of impugned drugs have already been circulated to all the members.

		Alternatively, the members felt that there should be uniform guidelines from the DCG(I) for the effective recall of the sub-standard drugs. The format used for recall of the sub-standard drugs by the Joint Commissioner, FDA, Maharashtra, was circulated. The Chairman requested Commissioner, FDCA, Gujarat to look into the matter and examine the recall system followed by the FDA, Maharashtra and suggest DCG(I) in framing guidelines in the matter.	
4.	Matters concerning grant or renewal of loan licences to manufacture Large Volume Parenterals (LVPs).	In the 31st DCC meeting, the members decided that FDCA, Gujarat and FDA, Maharashtra would forward information regarding loan licences on LVPs to enable the committee to examine the matter from the legal angle. Since the complete information could not be furnished in time, the 32nd DCC decided to reconsider the matter. After listening to various comments, the Chairman decided that the issue will be reviewed by the Commissioner, FDCA, Gujarat and he should be assisted by the Joint Commissioner, FDA, Maharashtra. The Chairman requested	The matter was to be reviewed by the Commissioner FDCA, Gujarat. The report is not received. A fresh agenda is included in 33rd DCC by Drugs Controller, A.P.

		Commissioner, FDA, Gujarat to furnish his report within a period of 3 months time.	
5.	Consideration of the proposal to amend Schedule F-II in respect of standards for surgical dressings, viz. Gauge and bandages.	The Agenda came up in the 31st DCC meeting. As per Schedule F-II for the manufacture of gauge and bandages, cotton yarns count between 20 tex and 25 tex for wrap and count between 25 tex to 30 tex for weft has to be used to maintain the higher weight of 30.5 gms. per sq.m. and 57.5 gms. per sq. m. respectively. The other Pharmacopoeia viz. BP, USP and EP prescribe cotton yarn 40s count for weaving the gauge and bandage cloth and the required weight is only to maintain a minimum weight of 14 gms. per sq. m. for gauge and minimum 28 gms. per sq. m. for bandage. Cost-wise the gauge and bandage manufactured with cotton yarn count of 40s is cheaper by 50%. It has been suggested that the standard of bandage cloth and the gauge should be made at par with the standard of other pharmacopoeia such as BSP, USP and EP. The 31st DCC members desired to generate comments on this issue from BIS.	The matter was referred to the Director, BIS opinion. The Director, BIS required the performance appraisal report of the cotton gauge and bandage cloth conforming to the construction particular to other Pharmacopoeia viz. BP, USP from the manufacturer gauge and bandages. The said information has been forwarded to Rajapalayam Chamber of Commerce necessary information.

		Since there is no reply received from BIS, the members of the 32nd DCC desired to pursue the matter with the BIS to have a complete report in the matter.	
6.	Consideration of inclusion of all Schedule "G" drugs in Schedule "H" and the resultant omission of Schedule "G" from the Rules.	The sub-committee constituted by the 31st DCC requested for some more time to complete the report. The members agreed to provide time till 31st December, 1998 as desired by the sub-committee.	The subcommittee entrusted with the task is yet to submit its report. The matter may be reviewed afresh.
32nd DCC ATR			
7.	Gradation of the penalties for offences under the Drugs and Cosmetics Act and Rules thereunder and setting up special court for cases where CrPC is not required to be followed.	The members discussed the matter in detail. The Section 27 of the Drugs and Cosmetics Act related to the penalties of offences for manufacture, sale, etc. in contravention of Chapter IV is to be examined well before making any recommendation on the penal offences. In some of the States, as in West Bengal and Uttar Pradesh, the penalties have been made much stringent by providing "Life imprisonment" in clause 'a' of Section 27. Thus, provisions for compounding of offences should be recommended only after the careful study of the particular section of the	The DCC recommended a subcommittee under the Chairmanship of Drugs Controller, Karnataka to examine the issues. The report of subcommittee is not received. A specific request for such proposal has again received from Kerala for consideration in 33rd DCC.

		Act.	
8.	Deletion of clause (a) from the provisions of Chapter IV under "Extent and conditions of exemption" – entry 13 of Schedule K of Drugs and Cosmetics Rules (House Hold Remedies).	The matter regarding the introduction of OTC drugs in the Drugs and Cosmetics Rules has been discussed at length. On the basis of the recommendations made by the members, the Chairman desired that the following sub-committee will examine the matter and give their recommendations for taking necessary action in the matter	Report of subcommittee is placed. Member may consider the report.
9.	To change the designation from Inspectors to a suitable designation befitting importance of their role to perform the work under the Drugs and Cosmetics Act and Rules thereunder.	The members desired that the proposal to change the designation of the Inspectors may be examined by the Expert Standing Committee to assess the feasibility of the proposal in relation to the performance of the duties of the Inspectors under the provisions of the Drugs and Cosmetics Act and Rules thereunder.	The matter was referred to Expert Standing Committee for examination. The report is not received.
10.	Proposal for making standards for diagnostic kits and reagents.	The issue for laying down the guidelines for the manufacture, quality control parameters and identification of nodal testing laboratories, etc. has already been discussed in the Expert Committee meeting held on 10th July, 1998 at Nirman Bhawan, New Delhi. In the meeting, the committee proposed	It was decided that the subject proposal would be placed in the next follow up meeting of Diagnostic Expert Committee for consideration and framing the guidelines. Since, the Diagnostic Expert Committee could not meet and standards for diagnostic kits especially for blood banks are essentially needed for regulatory control. DCC may consider to refer the

		for three sub-committees to examine the quality control parameters of the diagnostic kits and reagents which are presently manufactured and imported in the country. Once the reports of the sub-committees are received by the Drugs Controller General (India), a decision will be taken on the basic issues related to the quality parameters to be followed for the imported and indigenously manufactured diagnostics. The members have also been requested to give their views for laying down the guidelines for the manufacture and quality control of the imported and indigenously manufactured diagnostics. The attending member, Dr. (Mrs.) Sokhey of National Institute of Biologicals, New Delhi recommended that each lot of the imported critical kits should be tested before being released in the market. At present, NIB, New Delhi is testing the critical kits.	issue to NIB, NOIDA to frame necessary standards in this regard.
11.	Availability of Morphine tablets to the cancer patients.	The item relating to the availability of morphine tablets to the cancer patients has been introduced by the Chairman. Smt. Reva Nayyar, Joint Secretary (Admn. and N.C.), Department of	The DCC recommended a subcommittee to examine the proposal. Considering the importance of the matter the report of subcommittee was placed before the DTAB for making suitable entry under Schedule

		Revenue, Ministry of Finance, illustrated the matter that in response to a Public Interest Litigation matter, the Narcotic Control Board has been asked to find out a suitable simplified procedure, so that morphine tablets are easily available to the out door cancer patients, but the procedure should not dilute the concern of the possibility of the abuse of the drug. In this connection, she requested the members to examine the possible amendments of the relevant rules and schedules of the Drugs and Cosmetics Act and Rules thereunder to facilitate the sale of morphine tablets by the recognized institutions to the out door cancer patients. A draft guideline has been circulated to all the members on the special provision relating to the availability of morphine tablets by recognized medical institutions.	'K' of the Drugs & Cosmetics Act and Rules. The draft notification has since been published.
12.	Proposal for consideration of amendment of Schedule 'M' on Good Manufacturing Practices (GMPs) and requirements of premises, plants and equipments.	The Agenda relating to the Good Manufacturing Practices on production and quality assurance has been introduced by the Chairman. Schedule 'M' pertaining to the GMP and requirements of premises, plants and	The issue was followed up through a separate special DCC agenda held on 26/6/99. So far as GLP concerned, the report of subcommittee is placed for consideration. Revised Schedule M is to be notified shortly.

		equipments was incorporated under the Drugs and Cosmetics Rules in the year 1988. WHO with a view to control the quality of drugs moving in the inter-country markets devised a 'Certification Scheme' on the quality of the pharmaceutical products available in the international commerce. Most of the countries are participating in the 'WHO Certification Scheme' through their respective National Health Authorities. WHO in its 28th meeting, adopted the revised text of the 'Good Practices' in the manufacture and quality control of drugs and published revised guidelines from time to time. It has, now become necessary to review the existing Schedule 'M' under the Drugs and Cosmetics Rules and to modify it at par with the WHO requirements as India is also one of the participating country to WHO Scheme.	
13.	Consideration for the amendment of Rule 85(2) so that powers to the licensing authority cannot be challenged by the appellate authority or the Court.	The members discussed the matter and decided that the issue relating to the amendment of Rule 85(2) may be initially examined by the Expert Standing Committee. Accordingly, the Chairman decided that the Expert Standing Committee may examine the matter and forward their	It was decided that Expert Standing Committee would examine the matter and forward their recommendations to Chairman. No recommendation has been received in this regard.

		recommendations.	
14.	Consideration of the question whether sanitary pads be classified as drugs.	The Chairman requested the Assistant Drugs Controller (India), Silvassa to forward the copy of the judgement given by the Hon'ble Bombay High Court, to take further necessary action in the matter.	Recently, a copy of judgement has been received from the Drugs Controller, Goa, which is under examination.
Supplementary Agenda Items			
15.	Consideration of extension of shelf life of Rifampicin capsules in Schedule 'P' in Drugs and Cosmetics Rule and modification of packaging of Ethambutol tablets.	Both the issues, extension of shelf life of Rifampicin capsules and packaging system of Ethambutol tablets were discussed in the meeting. Dr. Tom Frieden, the guest member from WHO, SEARO, explained the current scenario in the global market in respect of shelf life of Rifampicin capsules and packaging of Ethambutol tablets. All the members agreed that necessary stability studies are required to be performed to consider the extension of shelf life of Rifampicin capsules and also to select proper packaging system for the Ethambutol tablets. The Chairman requested Dr. Vinay	After discussion, the Chairman requested that Dr. Vinay Nayak of M/s. CIPLA as an expert member to furnish his views. After reviewing the comments the Director, CIPL, Ghaziabad, requested him to provide stability data of other established manufacturers similar products for further examination. The study is in progress.

		Nayak, the expert member to take up the issue and to forward necessary guidelines to be taken up by the Committee.	
16.	Use of Saccharin Sodium and other artificial sweeteners in oral liquids and other preparations meant for paediatric use.	The recommendation for the use of Saccharin Sodium in paediatric preparations made by the Indian Pharmacopoeia Committee has been discussed in the meeting. The Chairman decided that once the minutes of I.P. Committee will be received, the matter will be circulated to all the members and experts. The DCC will take the decision after obtaining the comments from the experts.	Consequent upon the decision taken in the meeting, the matter was referred to IP Committee for discussion IP Committee in its meeting agreed to the proposal. Accordingly, the amendment in IP has been issued.
17.	Consideration of the proposal for introducing new sections in the Drugs and Cosmetics Act for offences committed by an approved testing laboratory.	The members discussed the matter in the meeting. At present, Drugs and Cosmetics Rules (Rule 150-k) permits withdrawal and suspension of approvals given to the approved testing laboratories. However, there is no penal action prescribed under the Act in respect of the offences committed by an approved testing laboratory. In this connection, it may also be noted that there is no statute of an approved laboratory under the provisions the Act.	After discussion, the Chairman requested the Drugs Controller of Govt. of NCT of Delhi to review the agenda and forward a draft proposal justifying the incorporation of penalty clause at appropriate place of the Act for offence made by approved laboratory. No such proposal has been received so far.

		The members requrested the Drugs Controller, Delhi to review the Agenda and to forward a draft proposal justifying the incorporation of the penalty clause at the appropriate place of the Act for offences made by an approved laboratory.	
18.	Proposal to make amendment in Rule 148(1)(b) related to the manner of labeling of cosmetic products.	The Commissioner, FDCA, Gujarat referred the existing provisions of Rule 148(1)(b) wherein it is mentioned that the inner and outer label of a cosmetic product should provide the name and principal place of business of the manufacturer. He desired that the words "principal place of business" may be substituted by the words "address of the manufacturing premises". The Chairman decided that the matter may be taken up by the Expert Standing Committee for necessary examination and recommendation.	Based on the decision taken, the matter has been referred to Expert Standing Committee for examination and recommendations. The report of Expert Standing Committee is not received.
19.	Consideration to make amendment in Section 25(4) of the Drugs and Cosmetics Act, pertaining to the report of the Government Analyst, and some changes in Forms 27, 28, 27-A, 28-A, 27-F, 28-F, 28-D,	The Commissioner, FDCA, Gujarat desired to have some changes in some of the Sections of the Rules as well as in some Forms under the Drugs and Cosmetics Rules as mentioned in the title of the Agenda. For this purpose, he brought certain write-ups on 22.9.1998	The matter has been referred to Expert Standing Committee for examination and recommendations. The report of Expert Standing Committee is not received.

	27-D and in Rules 27, 75(A), 76, 79(A), 65(2) and 66 of the Drugs and Cosmetics Rules.	for the DCC meeting. However, the Agenda items were not much clarified in his write-ups and could not be discussed in detail in the open meeting. On his permission, the Chairman suggested that he may take up the issues with Expert Standing Committee for necessary examination and recommendations.	