MINUTES OF THE 34th MEETING OF THE DRUGS CONSULTATIVE COMMITTEE HELD ON 8th & 9th APRIL, 2002

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MINUTES OF THE 34TH MEETING OF THE DRUGS CONSULTATIVE COMMITTEE HELD AT NEW DELHI ON 8TH & 9TH APRIL, 2002

Thereafter the agenda items were taken up for discussion.

A. **CONFIRMATION OF THE MINUTES OF THE 33RD DCC MEETING HELD ON 30TH & 31ST AUGUST 2000.**

The Committee unanimously agreed to the minutes of the 33rd DCC meeting held on 30th & 31st August 2000.

The Chairman noted that the earlier Sub-Committee has not done its job. He requested Shri. R. Narayanaswamy to act as a Member Secretary of the Sub Committee and to examine the issues as quickly as possible. If required Director CIPL, Ghaziabad and representative of BIS may be co-opted in the sub committee to resolve the issue.

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 Chairman informed that in the last meeting it was decided that the members would cover their specific comments on the report of the Sub Committee, which had examined the proposal. In the absence of any specific comments on the report of the sub committee, it may now be appropriate to consider the recommendation as approved and action to be taken as per the recommendation of the report.

The Chairmen further informed that majority of the products, which are commonly sold as OTC (over the counter) have already been covered under the Schedule K exemption. Majority of these products are safe and are used in self-limiting type of disease/disorders.

After discussion, it was decided that the recommendation of the sub committee on the proposal, may be referred to DTAB for taking further 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 & Rules thereunder.

The sub committee under the chairmanship could not meet and submit its report to the DCC. The Chairman, however informed the Members that in the State of Rajasthan the designation of 'Drugs Inspector' has been changed to 'Drugs Control Officer' by a circular. issued by the State Government. In the light of the Rajasthan Govt. decision, the Chairman advised the member that the proposal may be got examined by the respective State Govt. authorities in the matter of changing the designation.

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.

During discussion, it was felt that adequate safeguard has already been prescribed under the Act to make 'stop production order' and to issue show cause notice by the Licensing Authority. Drugs Controller, U.P. informed that opportunity need to be given to the applicant as per rule 85(2) before cancellation of the licence. DC, Goa informed that appellate decisions can be challenged before the court of law.

After discussion, it was decided that the report of the committee was purely advisory and each State Licensing Authority may decide on the merit of the cases.

SUPPLEMENTARY AGENDA ITEMS OF 32ND DCC MEETING DATED 22ND /23RD SEPTEMBER 1998.

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.**

During discussion, DC Delhi informed the members that under the Act, there is no penalty clause through which approved testing laboratory can be penalized in case the testing laboratory commit any offence or testing is performed not in conformity to the GLP and therefore it is imperative to amend various sections to regulate the approved testing laboratory as per the proposal prepared by their Deptt. DC, Goa informed that testing Laboratory is a part of the activity covered under the condition of licence for manufacturing of drugs for sale and any violation of the licensing condition, the action may be taken against the firm including the testing lab.

Since the draft proposal made by DC Delhi requires amendments under the Act, the chairman requested DC Delhi to modify the draft proposal in such a way so that it may be required to amend only the rules, in order to regulate the approved testing Laboratory.

Item No. 7.2: **Consideration to make amendment in section 25(4) of the Drugs & 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.**

After discussions, it was decided that members would furnish their comments on the report of the sub-committee within 3 months time period failing which it would be presumed that the members are in agreement with the report of the committee.

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 Certification Scheme, and after each inspection the Inspector record comments on compliance of GMP's in a register specially maintained at the manufacturer's location.**

The Chairman informed that as an off-shoot of the above recommendation, it was decided to have common certification formats. The report prepared by expert group on uniformity of the formats were circulated to members for comments. However, only DC Delhi commented on the various formats and the same were again sent to members for examination. Since no comments have been received and as the issues relate to NHRC, the chairman specifically asked DC Andhra Pradesh convey her comments on the reviewed formats.

In the absence of any specific comments from the members, it was unanimously decided to adopt the report prepared by expert group on uniformity of the formats which would serve as a guideline to drugs control authorities.

CONSIDERATION OF THE ACTION TAKEN REPORTS BASED ON AGENDA RELATED TO THE 33RD DCC MEETING HELD ON 30TH AUGUST AND 31ST AUGUST 2000.

Item No. 1 : Regulatory Control on Medical Devices.

After in-depth discussion on report of sub committee on medical devices, it was decided that the report needs to spell out the types of devices which need to be regulated under the Drugs & Cosmetics Act, nature of training which is to be imparted to Regulatory agencies and indicate the laboratories which could undertake the testing of such devices.

Accordingly, the Chairman of the sub-committee was advised to review the report in the light of these issues and convey detailed recommendation. WHO guidelines on medical devices and the regulatory practices in other countries also be examined by the committee. BIS may also be involved in the deliberations.

Item No. 2 : Recycle of used disposable needles and syringes in health care System.

During discussion, it was informed by the members that no instances have been reported regarding recycling of used disposable needles and syringes in the Health care system in their State.

Accordingly, it was decided that no action is required on the proposal.

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

Based on the opinion received from leading anesthetist about use of oxygen from in-house oxygen extraction plant, members were of the consensus opinion that 93% oxygen is reported to be safe in the medical practices. It was, therefore, decided that an exemption under Schedule K may be provided to the Government hospitals for its captive consumption of 93% oxygen.

During discussion, issue was also raised as to how does one send a sample of medical oxygen to Government testing lab and which labs could undertake such testing. It was decided that Director CDL, Kolkata and CIPL, Ghaziabad, would work out the logistics for sampling of oxygen to be sent to them for testing etc.

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

Members informed the Chairman that no such instances have been reported regarding branding of drugs for Ayurvedic to escape price control, however, if any such cases reported, the same is referred to NPPA.

Generally, many borderline products like pain balms which contain such ingredients for which refernce may also be available in ayurvedic texts, have been switched over as ISM drug which do not require licence for sale.

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 requested the Chairman of the sub-committee to initiate the working of the sub-committee in order to examine the proposal and furnish its report within three months time.

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.

Considering the specific technical expertise and specilised facilities required for manufacturing quantity products which are to be formulated as LVPs, the DCC unanimously accepted the recommendation of the sub committee for the amendment of the concerned Rules under the Drugs & Cosmetics Act so as to regularize the manufacturing of LVPs under loan licence till such time that loan licensing is an integral part of rules.

It was agreed that there has been an omission in the forms pertains to CLAA in this regard and many drug formulation in large volume continue to be manufactured under loan licence arrangement as such skill may not be available with many industries. This correction, however, needs to be limited to LVPs.

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

Please refer to the minutes of item no. 33.

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

The committee agreed with the comment of the Director CIPL on the proposal regarding necessity to amend Schedule V requirement so as to conform to the requirement of IP in respect of prescribing uniform limit of net content of liquid oral forms.

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

The Committee agreed with the comments of Director CIPL in respect of rubber and dotted condoms regarding standards to be complied with the statutory requirements as applicable to other condoms.

Further, Chairman informed that the comments in respect of limits of preservatives in ophthalmic preparations would be communicated as and when it is received from Director CIPL.

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

After discussion, it was decided that protocol for possible drawing of blood for testing should be got examined through the sub committee under the Chairmanship of DC, Karnataka. The member of the sub committee would be as under :

Drugs Controller, Karnataka	-	Chairman
Jt. Comm.FDA, Maharashtra	-	Member
Drugs Controller, Kerala	-	Member
Representative of NACO	-	Member
Shri. R. Narayanaswamy, DDC(I)	-	Member secretary.

Item No.41.3: Dextropropoxyphen, Ephedrine hydrochloride, Amphetamine, Buprenorphine hydrochloride should come under Schedule X licence.

During discussion, the members opined that many products having pharmacological activity related to Morphine are distributed through retail outlet without being covered under Schedule X.

The Commissioner, FDCA, Gujrat informed the committee that Buprenorphine may be reported to be misused in certain parts of the country specially in North Eastern area, however since buprenorphine is a potent analgesic, it would not be appropriate to ban the drug throughout the country. Its manufacture and distribution may, however, be regulated by prescribing strict regulatory norms. The Director, Drugs Control, Sikkim informed that buprenorphine may be less abused than the benzodiazepine group and it is also one of the drugs of choice in the moderate to severe pain especially when Morphine is not available. It was pointed out that once a drug is included in Schedule 'X', its availability, even for genuine medical needs become scarce.

The proposal be got examined through a sub committee under the Chairmanship of commissioner FDA, Maharashtra regarding its extent and abuse. The Committee may also co-opt the member from North East State and to include some more clinician using buprenorphine in the medical practice, preferably from de-addiction centre. The members of the sub-committee would be as under :-

The Commissioner FDA, Maharashtra	-	Chairman
The Comm., FDCA, Gujarat	-	Member
Drugs Control, Meghalaya, Assam And Manipur	-	Member
ADC(I), HQ (SDV)	-	Member Secy.

CENTRAL AGENDA ITEMS

Item No. 1 : Printing of labels and wrapper of drugs in Hindi.

During discussion, it emerged that Rule 96 of Drugs & Cosmetics Rules, which prescribes manner of labeling, does not stipulate about any specific language in which label is to be provided on drugs. The committee felt that making it mandatory to print label of drugs also in Hindi would require amendment to said Rule.

Members of DCC were of different opinion on the subject proposal. Members opined that printing of labels in Hindi as well as concerned Indian language may be considered as a voluntary activity. Certain manufacturers are already voluntarily publishing the drugs information in Hindi in labels and package insert.

The overall opinion was not in favour of introducing a mandatory clause as drugs are sold country wide and may then need printing of labels in different languages. The committee, however, noted that manufacturers have already been advised by DCG(I), through Indian Drugs Manufacturer's Association, in this regard.

Item No. 2 : Stricter check on selling of antibiotics across the counter under valid prescription.

The Committee noted the issue in the news item, which appeared in the Economics Times dated 3/12/01 about the indiscriminate use of antibiotics.

During discussion on stricter check regarding sale of antibiotics across the counter, It emerged that antibiotics are already covered under Schedule H to the Drugs & Cosmetics Act and are required to be sold against the prescription only. The Chairman suggested to the members that each Chemist and Druggist Association of their State may be advised to sell the antibiotics against the prescription of RMP's only, and to educate their members about the consequences of indiscriminate use of antibiotics. The Chemist / Pharmacist who have a direct interaction with patient, should also advise them about proper use of antibiotics. They should also coordinate with prescribers in this regard.

Item No. 3 : Proposal to increase the shelf life of freeze dried BCG vaccine.

After discussion, member unanimously agreed with the proposal to enhance the shelf life of freeze dried BCG vaccine to two years under Schedule P to the Act.

Item No. 4 : Proposal to review expiry period of Erythromycin raw material and Erythromycin Estolate for oral suspension under Schedule P of Drugs and Cosmetics Act and Rules.

Members opined that the whole Schedule P needs to be reviewed in the context of shelf life. It was noted that different countries adopt different regulatory scheme in this matter. Moreover, pharmacopoeia, separately prescribes storage conditions. For bulk drugs, it is seen, that the practice is much different than what is prescribed in Schedule P. The Chairman felt that there must have been international norms for establishing expiry of bulk drug and its formulation.

Based on the discussion held with the members, it was decided that whole Schedule P should be got reviewed through a committee under the Chairmanship of Commissioner FDCA, Gujarat. The Committee would also examine the international practice followed in assigning the shelf life of bulk drugs and its formulations. The member of the committee would be as under :

1) Commissioner FDCA, Gujarat	Chairman
2) Representative of FDA, Maharashtra	Member
3) D.C., Karnataka	Member
4) Director CDL, Kolkatta	Member
5) Dy. Drugs Controller (I) W/Z	Member
6) Drugs Control, (Andhra Pradesh)	Member
7) Director CDTL, Mumbai	Member Secretary

Item No. 5 : Proposal to consider renewal of drugs licence.

During discussion, members were of different opinion on proposal for grant or renewal of licence on Form 25 and 28 within a period of 3 months from the date of receipt of application as stipulated in Rule 154 of the Drugs & Cosmetics Rules.

Director Drugs Control, AP suggested that if certain check list is devised for verifying the application submitted by the applicant, it would hasten the regulatory process for clearance of the licence. The Chairman desired that there is a need for proactive action in issuing the licence within 3 months time period as validity of the licence has now been enhanced to 5 years which would reduce the overall burden of inspection.

Given 3 months time period for issue of licence on Form 25 & 28, it requires an amendment under the Drugs & Cosmetics Rules and therefore it was decided that renewal of licence in Forms 25 & 28, in three months may be considered as desirable and not as a statutory requirement at present.

Item No. 6 : Action to be taken on the recommendations of the regional consultation on Public Health and Human Rights organised by NHRC (vide its recommendation no. 6(b)).

The Committee noted the recommendations of the regional consultation on Public Health & Human Rights organized by NHRC. It was felt that appropriate initiatives have already been taken to implement the suggestions. Funds are, however, a major constraint. The capacity building project and computer network being pursued by the Department of Health, GOI would be a further step in the direction recommended by NHRC.

Item No. 7 : Proposal to incorporate printing of Government logo and product name for government supply.

After discussions, it was decided that printing of Govt. logo and product name on the outer circumferences of capsules cannot be considered as a statutory provisions under the labeling requirements to the Drugs and Cosmetics Rules. However, it may be left, to the purchasing agencies for printing the Govt. logo on outer circumferences of the capsule as per their tender specifications.

Item No. 8 : Sale of drug including narcotic & psychotropic substances through internet.

During discussion, it emerged that use of internet for commercial purposes is inevitable and the regulatory agencies may find it difficult to stop such activities as law does not prescribe specific condition. The Chairman informed to the members that the sale of drugs throght internet have been enforced in US FDA.

It was decided that the issue may be got examined through Delhi Pharmaceutical Trust who has expertise and information about emerging pharmacy practices around the world.

Item No. 9 : Storage conditions for medicines at retail pharmacies.

A detailed presentation on the underlying issues was made by Dr. D.B.A. Narayanan. The committee noted the various situations emerging out of the survey conducted at 100 retail pharmacies in Delhi by Delhi Pharmaceuticals Trust and appreciated the initiative taken by DPT which is in the interest of Pharmacy professionals, consumers as well as is useful to the regulatory authorities.

Dr. Narayanan was requested to suggest specific changes in Rules as well as in IP in this regard. While circulating the report of the survey, the Chairman requested the members that emerging issues need to be properly addressed by the concerned agencies.

Item No.10 : Harmonisation of Schedule 'O' relating to the standards of disinfectant fluids (black & white and other fluids).

DCC accepted the proposal for harmonization of Schedule 'O' relating to the standards of disinfectant fluids (Black & White and other fluids) at par with the standards prescribed by BIS.

Item No.11 : Submission of reports on psychotropic substances.

The special invitee Sh. Subha Rao, Asstt. Director, NCB, R.K. Puram expressed deep concern on reported delay in furnishing information in Form P and Form P/B by the State Licensing Authorities for onward transmission to INCB, Vienna. He further informed that such information is essential for inferring the overall status of Psychotropic substances available in the country. The proforma designed by INCB was circulated to the members and Sh. Rao requested the members that the desired information is to be supplied in the manner prescribed in the proforma.

The members, however, pointed out that many of the products which are mentioned in the proforma are not in existence in the country and the information could only be communicated in respect of bulk drugs and not its formulations.

Finally, it was decided that the required information as per the proforma circulated should be got sent directly to the NCB, R.K.Puram under intimation to DCG(I) office without any delay. The information should be based on the bulk drugs actually licensed in each State.

Item No.12 : Issues referred by NPPA for discussion with State Drugs Controllers.

The proceedings of the discussions held by the members with the Chairman and officials of NPPA would be circulated separately.

Item No.13 : Proposal to prescribe Forms in which licence to manufacture Ethyleneoxide gas for sterilization be considered.

During the discussion, it emerged that the minimum requirements for the production of Ethylene Oxide used for sterilization of medical products has been prescribed under Schedule M III to the Drugs & Cosmetics Rules, and in the absence of any specific category of Form in which

licence to be granted, the various State Licensing Authorities are granting the permission for sterilization in From 25, 28, 32 and 25D etc.

Since the members were of different opinion on the proposal, it was decided that FDA, Maharashtra would furnish the status paper regarding the licence in which the permission for Ethyleneoxide Gas sterilization may be considered.

Item No.14 : Proposal to consider the uniform implementation of the validity period of licence vide Nnotification GSR No. 894(E) dated 11.12.2001.

While discussion on revised Schedule M vis-à-vis validity of the licence period, the Commissioner FDCA, Gujarat proposed that validity of the licence may be in calendar year and the validity period of 5 years may be counted from the date and year in which the licence is granted. This would streamline the licence period in line with the WHO validation period and the Licensing Authority would be in position to monitor pending renewal cases.

However, Chairman explained the genesis of changing the pattern of validity period and its advantage. This was accepted by members.

Item No.15 : Proposal to consider issuance of WHO GMP Certificate for Homoeopathic / Herbal medicines and surgical dressings.

The issue was discussed at length and members opined that issuance of WHO GMP Certificate can be considered if WHO prescribes guidelines for the products proposed to be considered for acquiring WHO certificate and in the absence of such guidelines, product may not be considered for WHO Certification. Dy. Drugs Controller (I), CDSCO, West Zone, informed the members that WHO prescribes guidelines for Herbal products and therefore may be considered for WHO Certification. As regards to the issuance of WHO GMP Certificate for Surgical Dressings and Homoeopathic products, DC, Goa desired that DCG(I) may issue guidelines on these products to be followed uniformly through out the country. In the context of WHO guidelines, Chairman informed that such guidelines are very specific and vary from product to product.

After prolonged discussion, it was decided that the proposal may be taken up with WHO office for advice etc.

Item No.16 : Movement of banned drugs.

The overall information from members indicated that instances of deliberate sale of banned / phased out drug have not been observed. However, it was decided that each State Drugs Controller would continue

to furnish report in respect of movement of banned formulation in their State.

Item No.17 : Proposal to consider the extent of concession to be provided to veterinary vaccine unit owned by the State Government in the context of revised Schedule M.

Deputy Drugs Controller (I), West Zone explained difficulties in regulating the production of vety. Vaccines by State owned units and if the concept of newly constructed GMP is enforced, there would be chances of closure of such units. Further, he added that such units are mother institutes catering to the vaccine needs of State Govt. agencies. If such units are closed, then immunization programme would be affected.

To consider the proposal in the light of newly revised enforced GMP, it was decided that the matter would be followed up with the concerned State Govt. under which such units exist, by the office of DCG(I).

Item No.18 : Proposal to consider for discussion the relaxation clause in respect of testing laboratories under Schedule 'F' to the D&C Act.

Since the State Licensing Authority were of different opinion on the proposal, it was decided that matter may be referred to Committee examining Blood Bank related issues.

Item No.19 : Action taken by the Govt. on the recommendation contained in the 15th report of the Standing Committee on Petroleum and Chemicals (2001) on "Pricing & Availability of Drugs /Pharmaceuticals" (Item No. 15).

The Committee noted the recommendation of 15th report of the Standing Committee on Petroleum and Chemicals (2001) on "Pricing & Availability of Drugs / Pharmaceuticals."

During discussion, the members informed that the Chemist Shop attached with Nursing Home is already covered under the Sale Licence as per the provisions of Drugs & Cosmetics Act and Rules and, therefore, they are held responsible for every wrongful act done by them. However, the qualified doctors are exempted under the Schedule K for supplying the medicines for their own patients.

It was informed by members that many RMPs stock large quantity of drugs resembling a medical store. In case, if the qualified doctors is required to be covered under the provisions of Drugs & Cosmetics Act & Rules for the purpose of grant of licence, and category of the medicines

required to be stocked for supplying to their own patients, the matter may be referred to Indian Medical Association for their concurrence.

Accordingly, the DCC recommended that matter may be referred to IMA for opinion.

Item No.20 : Uniformity in the licensing procedure.

The Chairman took a stock of the situation prevailing in States regarding Licensing Authorities approach for approval of formulations.

After considering the views of the members, the Chairman requested that serious attempt need to be made to harmonize the drug regulatory practice in the country in every aspect. Rules are being amended for the purpose. However, even within the ambit of existing provisions, it is difficult to understand the deviations observed in the working of some State Licensing Authorities. This is creating an abnormal situation.

STATES AGENDA ITEMS

ANDHRA PRADESH

Item No.21 : Proposal to consider the time limit for the issuance of certificate by the Govt. Analyst in Form-13 read with Rule 57 under the Drugs and Cosmetics Act, 1940 and Rules thereunder.

Director, Drugs Control. AP informed the Committee that time limit has been prescribed for issuing a certificate of test / analysis by the Govt. analysts under the PFA Act & Rules and if similar provision should also be made by respective State Govt. or the Drugs Control Organisation. Some members were of the view that perhaps a cut- off date may be decided and product approved prior to that may be examined separately. However, keeping in view the logistic problems, members were of the opinion that time is not ripe to prescribe a statutory time limit under the D & C Act and Rules thereunder which would expedite the prosecution process in case the drug is declared to be of not of standard quality.

Item No.22 : Drugs and Cosmetics Rules, 1945 Enhancement of fee structure GSR No. 601(E) dated 24.8.2001.

The Chairman clarified the various issues raised by Drugs Control, AP and the Commissioner, FDCA, Gujarat regarding enhancement of fee structure under GSR No. 601(E) dated 24.8.2001.

The Committee also noted the circular of the office of the Drugs Controller General (I) in this regard.

Item No.23 : **Proposal to consider amendment under Rule 65 so as to allow the maintaining of records through electronic data processing system.**

It was decided that there is no immediate need to amend Rule 65 so as to prescribe maintaining of records through electronic data processing system . Hard copies in any way are required to be maintained as per the prescribed rule.

Item No.24 : **Clarification regarding duties of Inspectors prescribed under Rules 51& 52.**

DC, AP informed the Committee that recently in one of the writ petitions, the Hon'ble High Court of AP has upheld the decision that the drugs inspector need not take the permission of the Controlling Authority to launch a prosecution as stipulated under Rules 51 & 52.

DC, Kerala suggested that the judgement needed to be examined in the light of the rules 51 & 52 so as to understand the spirit of judgement before the rule is amended.

Finally, the DCC decided that the DC, AP would forward the judgement to DC Kerala and Karnataka for examination and opinion. It was, however, uniform opinion of all members that no organization can function smoothly without a review system in place of supervisory level, specially in regard to prosecution etc.

DELHI

Item No.25 : **Consideration for amendment of Rule 148 of the D&C Rules 1945, for incorporating the labelling/marking requirements specified under Bureau of Indian Standards (BIS).**

After discussions, Committee agreed with the proposal of DC, Delhi to amend Rule 148 of the D&C Rules 1945 for incorporating the labeling / marking requirements specified under Bureau of Indian Standards (BIS) in the D&C Rules.

Item No.26 : **Consideration for amendment of Section 22 (2-A) of the D&C Act, 1940.**

After discussion, the DCC agreed with the proposal of DC, Delhi for amendment of Section 22 (2-A) of the D & C Act 1940 so as to make returning of seized documents optional, depending upon the request by person from whom the documents were seized.

Item No.27 : **Amendment in the qualification of Govt. Analyst.**

After discussion, members unanimously agreed to amend the qualifications of Govt. Analysts as per the lines suggested by DC, Delhi. This would enable a wider choice and would also enable the Govt. Drugs testing laboratories to function smoothly.

GOA

Item No.28 : **Consideration of the need to inform all State Licensing Authorites the details with reference to drugs cleared as 'New Drug' by Drugs Controller General (India).**

a) **THE COMPLETE SPECIFICATION OF FORMULATION**

After discussions, DCC agreed with the prosposal of DC, Goa regarding furnishing of specifications of bulk drugs and drug formulations; at the time of its clearance as a 'New Drug' by the office of Drugs Controller General (I). It was, however, reiterated that the provisions concerning drugs approval under Rule 122 A would be strictly followed by all State Licensing Authorities.

b) **The extension of permission granted to formulation on submission of post market surveillance studies after completion of two years.**

DCC agreed with the proposal, of DC Goa to furnish information on extension of permission granted to the formulations on submission of Post Market Surveillance studies after completion of two years by DCG(I) to State Licensing Authority so as to extend the validity of manufacturing permission.

Item No.29 : **Consideration of the question to amend Rule 94 of the Drugs and Cosmetics Rules at par with Rule 96(1)(iv) requiring to mention the complete address of the premises where the product is manufactured for export.**

The Chairman informed that the neutral code to be provided on the label of the product meant for export has already been considered earlier in the meetings of DCC and therefore does not require any amemdment to be incorporated under the D & C Act and Rules on the proposal.

Members agreed with the view.

Item No.30 : **Consideration of question to lay down Good Laboratory Practices under the Drugs and Cosmetics Rules.**

While explaining the proposal, DC, Goa, suggested that if the GLP guidelines are incorporated under the D&C Act and Rules, it would automatically have an impact on the quality of the drugs manufactured and also be in harmony with the revised Schedule M.

The Chairman informed that GLP guidelines were framed by the sub committee of DCC and, in general, speaks about the basic requirements to be provided by the laboratories and to be so audited by concerned approving authorities.

After discussion, it was decided that proposal be got examined by a sub-committee whether to incorporate the GLP guidelines under the rules itself and to suggest various amendments to be made in the rules.

The members of the sub-committee would be as under :-

Commissioner FDCA, Gujarat	-	Chairman
Incharge of FDA Maharashtra Drug Testing Lab.	-	Member
Drugs Controller, Delhi	-	Member
Drugs Controller, A.P.	-	Member
Drugs Controller, Goa	-	Member
Director, CDTL, Mumbai	-	Member-Secretary

Item No.31 : Consideration of the question to make suitable provisions for appointment of special court at district level to try the offences under the Drugs and Cosmetics Act and Rules.

After discussion, it was agreed that appointment of special court at district level for trial of offences is a State matter and members may seek the opinion through their law department on the proposal.

Item No.32 : Consideration of the question whether a "New Drug" which is cleared by Drugs Controller General (India), can be permitted to be manufactured by another company which has not obtained clearance, but intends to manufacture on 'principle to principle basis', from the unit which has obtained the clearance from Drugs Controller General (India).

While explaining the proposal by DC, Goa, it was informed by Commissioner FDCA, Gujarat that there is no statutory guidielines or rule to allow the firm to get the drug manufactured with different brand name from the firm which originally holds DCG(I)'s permission to manufacture a new drug. However, such permission may perhaps be granted on 'principle to principle' basis.

The Chairman informed the members that the proposal needs to be examined in the context of the Rule 122 A and the corresponding Schedule. After detailed deliberation, the members suggested to have the proposal examined by office of DCG(I) and to convey suitable clarification.

Item No. 33 : **Consideration of the question whether toilet soaps with the lable design to claim cosmetic value of ingredients like coconut milk protein / coconut oil, almond oil, ghee, milk, honey added in negligible quantity can be permitted.**

D.C., Goa explained the proposal in the context of the so called herbal cosmetics soaps which are frequently available in the market even as 'ayurvedic' preparation. There are exaggerated claims, though it may not contain specific herbs but small quantity of herbal extracts.

On discussion, it was agreed that a cosmetic preparation would remain cosmetic even if it contains one or two drops of herbal extracts or more as the final form would remain unchanged without loosing any physico-chemical property and therefore would be considered as only a cosmetic as per the definition prescribed under D & C Act and Rules.

As regard the proposal for surgical medical dressing which are being marketed as 'ayurvedic', the DCC recommended that the issue may be referred to Department of ISM & H for examination and opinion as there seems to be lack of clarity about such products.

At the same time, there is a need for best of GMP's and uniform enforcement to be applied to such surgical dressings.

GUJARAT

Item No.34 : **Proposal to consider the amendment under Section 25(3) as 'Drug Inspector or Manufacturer' in place of 'accused or complainant' under D&C Act.**

During discussion on the proposal, DC, Kerala informed the committee that in the State of Kerala, FIR serves the purpose of sending the sample for testing at CDL through the Court and therefore does not require any amendment to be made in Section 25(3).

The interpretation of the said Section varies from Court to Court based on the plea made by the complainant.

ADC, U.P. also stated that Section 25(3) should be read with the relevant Rule in order to present the case before the court so as to get the sample tested at CDL through the Court.

Since the members were of different opinion on the proposal, it was recommended that at the moment there is no need to make any changes in Sec. 25(3).

It was informed by the Chairman that there has been a Supreme Court judgement regarding manufacturer to receive a sample portion before launching any prosecution. This also has a bearing on this issue. The same is, therefore, to be separately examined which also has a bearing on this issue.

Item No.35 : Proposal to consider action to be taken under Rule 85(2) for different offences as a part of Good Regulatory Practices.

While explaining the proposal, it was informed by the Commissioner FDA, Maharashtra that the suspension of manufacturing activity wholly or in part depend upon case to case examination and State Licensing Authority has been empowered.

After discussion, it was felt that there is need to frame a suitable guidelines on the nature of warning with the corresponding penalty under rule 85 (2) which would be adopted uniformly by the Licensing Authority.

Accordingly, DCC recommended that proposal be got examined through a sub-committee under the Chairmanship of Commissioner FDA, Maharashtra.

The members of the committee could be as under :-

Comm., FDA, Maharashtra	-	Chairman
Comm., FDCA Gujarat	-	Chairman
DC, Orissa	-	Member
DC, AP	-	Member
DC, Goa	-	Member Secretary

Item No.36 : Product permission with more than one brand name.

Since the proposal had been discussed in the earlier meetings of DCC, it was decided that no further discussion is required at this stage.

Accordingly DC, Gujarat withdrew the proposal.

KARNATAKA

Item No.37 : Approval of competent technical staff for manufacturing.

Considering the advances in Research & Development and Specialization of many therapeutic products, DCC agreed that the period of experience of qualified personnel under Rules 71 & 76 may be relaxed for highly qualified technical person holding Post Graduate or Doctroate Degree or specific qualification best suitable for the particular activity.

Item No.38 : Submission of product development data by the licensee/applicant before granting permission to manufacture these drugs.

In the context of revised Schedule M, the Chairman explained to the members progressively the manufacturer should be required to generate product development data for which permission is to be sought from the Licensing Authority. The industry has to be explained the international requirement in this regard and the basic scientific reasoning in the context of principles of GMP.

Members agreed with the views of the Chairman on the proposal and suggested that while holding workshops, this issue may also be adequately explained to the stakeholders.

Item No.39 : Storage conditions to be incorporated in Form 17.

After detailed discussions, it was decided that at the time of drawing the sample under Form 17 the drug inspector would also make the impression regarding storage condition under which the sample was found stocked.

Item No.40 : Amendment to Rule 65(10).

After detailed discussion, members unanimously agreed with the proposal that Rule 65(10) be amended in such a way that definition of 'prescription' shall be applicable to all the rules given under the various parts in D & C Rules and not only to sub clause 9 of Rule 65.

Item No.41 : 'Note' portion giving discretionary powers to Licensing Authorities in Schedule M.

In the context of revised Schedule M, DC, Karnataka explained the difficulties being faced in licensing different categories of products for which the manufacturing requirements are not covered under the revised Schedule M e.g. Diagnostic Kits etc.

Based on the problem encountered by the SLA in issuing the licence, it was decided that the members would furnish their independent views justifying the need in providing the discretionary power by way of 'note' portion in the revised 'Schedule M'.

The sub committee for Schedule M need to examine this issue.

Item No.42 : Manufacture of Nutraceuticals, Cosmetics, Ayurvedic etc., in the licensed premises.

While explaining the proposal DC, Karnataka informed the committee that as per the present Schedule M in the 'note' portion, it has been mentioned as *the manufacturing premises shall be used exclusively for production of drugs and no other manufacturing activity shall be undertaken therein.* In the absence of any discretionary power, would it be appropriate to allow the manufacture of Nutraceuticals, Cosmetics, Ayurvedic etc. in the licence premises? In the proposal, DC Kerala informed that in the State of Kerala there is a different licensing authority for Ayurvedic and Allopathic drugs and therefore such situation may not arise.

After detailed discussion, it was decided that proposal be referred to the Sub-Committee constituted for revising the Schedule M for opinion.

Item No.43 : Inclusion of definition of 'premises' in Drugs & Cosmetics Act.

During discussion it emerged that existing provisions under the D & C Act and Rules is sufficient to take care of definition of 'premises' and therefore does not require any amendment to be incorporated in the D & C Rules.

Item No.44 : Inclusion of applicability of all the provisions of Cr.P.C.1973 for investigation in Section 22 and Section 32 of D&C Act.

After discussion, it was decided that DC Karnataka would seek the opinion of his law department on this issue and apprise DCG(I) about the same so that the matters can be articulated further.

MADHYA PRADESH

Item No.45 : Proposal to consider the incorporation of word 'counterfeit drug/cosmetics'.

The Chairman informed the committee that recently in the meeting of spurious drugs committee under the Chairmanship of DG, it was examined to in-corporate the definition of 'Counterfeit Drug / Cosmetics' under the Drugs and Cosmetics Act and Rules thereunder.

However, the committee observed that the existing definition of spurious drug does not cover the counterfeiting aspects and action can be initiated against the culprits.

Accordingly, the members concurred with the views of DCGI on the proposal.

Item No.46 : Proposal to consider mentioning of validity period of WHO GMP Certificate to five years.

In the light of the enhancement of the fee structure as well as validity of manufacturing period to five years, Commissioner, FDA MP and Maharashtra proposed that validity of WHO GMP Certificate should also be made at par with the manufacturing licence held by the applicant.

During discussion, the members apprehended that if the validity period of WHO GMP Certificate period is enhanced then the monitoring of the quality product moving in the international market would be difficult to achieve.

The Chairman informed the members that the issue regarding the validity of WHO GMP Certificate is to be examined with the practice followed internationally by various regulatory agencies.

Accordingly, it was agreed to gather information about various outside regulatory agency's practice in issuing the WHO GMP Certificates and then to take a policy view for taking further action.

In the meantime, the validity of WHO GMP Certificate be considered as 2 years.

Item No.47 : Consideration to prescribe modal procedure to be followed by the inspector whenever the Govt. Analyst report delivered by the Inspector is challenged by the dealer/manufacturer.

Please refer to the minute portion of Item No.34.

ORISSA

Item No.48 : Proposal to consider applicability of Section 23(5)(b) of D&C Act.

During discussion, DC Karnataka apprised the DCC that in case if the Judicial Magistrate refuses to receive and pass order for safe custody of seized drugs, the drug inspector may make an appeal.

Based on the feedback received from the members, it was considered that no action is required on the proposal.

Item No.49 : Proposal to consider amendment under Section 18(a) to the Act regarding sending a portion of the sample.

After discussion, it was decided that Section 18 (a) to the Act is a statutory provision and therefore it is mandatory to send the portion of sample to the addressee and therefore cannot be considered as a colossal waste of money.

However, the matter has to be intensively examined in the light of recent Supreme Court judgement related to a case in Rajasthan.

Item No.50 :Proposal to consider quantity of drugs samples required to be tested at CDL.

It was agreed that Director CDL would review the quantity of samples required for test / analysis as per the Pharmacopoeial specifications within three months time period. If required, Director CDL may also take the assistance of Director CDTL, Mumbai in this regard.

TRIPURA

Item No.51 : Misuse of Codeine Phosphate containing formulation.

After detailed discussions, it was general opinion that Codeine Phosphate has a medical importance and is an essential drug. It may, therefore, not be appropriate to consider the banning of all formulations containing Codeine Phosphate.

The committee is of the view that State Licensing Authority need to monitor the movement of such formulations in their State wherever instances of possible abuse are evidenced.

UTTAR PRADESH

Item No.52 : Variations in approvals of manufacturing / analytical chemists by different States.

Considering the variation in approvals of manufacturing / analytical chemists by different States, it was decided that the proposal may be referred to the sub-committee constituted for revising the Schedule M in order to review the modification for approval of competent person for the category of the drugs for which the permission is sought by the licensees.

Chairman was of the view that fundamentally the onus lies on the manufacturer to employ a technical person having prescribed qualification and appropriate experiences. Mere approval, would not provide a guarantee about the actual competence of such person.

WEST BENGAL

Item No.53 : Proposal for consideration in respect of allowing of grace period and reasons for framing guidelines for banned drugs.

Chairman clarified various points raised in the proposal made by the Director of West Bengal in respect of allowing of grace period in case of banned formulation and the reasons for framing present policy for formulations which are considered hazardous and the products which have been in use for long period but are considered to be lacking adequate therapeutic justification in the present context.

As regard to the 'stop selling' drugs in existence, the Chairman informed DC West Bengal that adequate safeguards have already been prescribed under the Act to deal with such situations. However, the earlier minutes of the meetings of DCC may be referred in this regard.

D.C., West Bengal appreciated detailed background provided about the issues under consideration and enlightening the DCC about deliberations held by DTAB on related aspects.

The meeting ended with vote of thanks to the chair.

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Annexure – I
(Item no. 2 of the 34th meeting)

Statement showing the action taken on the decisions taken at the 33rd Meeting of the Drugs Consultative Committee held in New Delhi on the 30th & 31st August 2000.

NO.	SUBJECT DISCUSSED	DECISION TAKEN	ACTION TAKEN
(1)	(2)	(3)	(4)
31st DCC MEETING			
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.	DCC requested the Commissioner, FDCA Gujarat to review the report of sub-committee from the angle of likely implications of restricting the number of Pharmacies in the country and also involve

		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.	the reviews of the trade association. Reviewed report awaited, vide letter no. 19013/2/2000-D dated 22/2/01.
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.	Director IVRI Izatnagar UP was requested to review the fee structure as proposed and discussed in the last DCC. It has now been informed by Dir.IVRI that fees structure as proposed has already been in practice vide letter no. STD/1/DC/2001/335 dated 23/3/2001.
3.	Consideration of the proposal to amend Schedule F(II) in	The Chairman noted that the earlier Sub-Committee has not done its job.	It was decided that proposal be examined afresh through sub-committee under the

	respect of standards for surgical dressings namely gauze and bandages.	He requested Shri. R. Narayanaswamy to act as a Member Secretary of the Sub Committee and to examine the issues as quickly as possible. If required Director CIPL, Ghaziabad and representative of BIS may be co-opted in the sub committee to resolve the issue.	chairmanship of DC (TN). Report of sub committee awaited.
32ND DCC MEETING			
4.	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 Chairman informed that in the last meeting it was decided that the members would cover their specific comments on the report of the Sub Committee, which had examined the proposal. In the absence of any specific comments on the report of the sub committee, it may now be appropriate to consider the recommendation as approved and action to be taken as per the recommendation of the report. The Chairmen further informed that majority of the products, which are commonly sold as OTC (over the counter) have already been covered under the Schedule K exemption. Majority of these products are safe and are used in self-limiting type of	The chairman requested the member to examine the report and furnish their comments before further action is initiated. No comment, received. Report may be considered for discussion so as to take final view in the matter.

		disease/disorders. After discussion, it was decided that the recommendation of the sub committee on the proposal, may be referred to DTAB for taking further action.	
5.	To change the designation from Inspectors to a suitable designation befitting importance of their role to perform the work under the Drugs & Cosmetics Act & Rules thereunder.	The sub committee under the chairmanship could not meet and submit its report to the DCC. The Chairman, however informed the Members that in the State of Rajasthan the designation of 'Drugs Inspector' has been changed to 'Drugs Control Officer' by a circular issued by the State Government. In the light of the Rajasthan Govt. decision, the Chairman advised the member that the proposal may be got examined by the respective State Govt. authorities in the matter of changing the designation.	The commissioner, FDCA Gujarat was requested to get the proposal examined through Expert Standing Committee. Report of committee awaited.
6.	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.	During discussion, it was felt that adequate safeguard has already been prescribed under the Act to make 'stop production order' and to issue show cause notice by the Licensing Authority. Drugs Controller, U.P. informed that opportunity need to be given to the applicant as per rule 85(2)	Report of the Expert Standing Committee was circulated to member for comments. No specific comments have been received. Report may again be considered for discussion.

		before cancellation of the licence. DC, Goa informed that appellate decisions can be challenged before the court of law. After discussion, it was decided that the report of the committee was purely advisory and each State Licensing Authority may decide on the merit of the cases.	
Supplementary Agenda items			
7.	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.	Director CIPL Ghaziabad was requested to examine the proposal after evaluating the stability data etc. Shelf life of Rifampicin capsule has now been amended under sch P after evaluating the stability data as well on the recommendation of DTAB.

		The Chairman requested Dr. Vinay Nayak, the expert member to take up the issue and to forward necessary guidelines to be taken up by the Committee.	
8.	Consideration of the proposal for introducing new sections in the Drugs and Cosmetics Act for offences committed by an approved testing laboratory.	During discussion, DC Delhi informed the members that under the Act, there is no penalty clause through which approved testing laboratory can be penalized in case the testing laboratory commit any offence or testing is performed not in conformity to the GLP and therefore it is imperative to amend various sections to regulate the approved testing laboratory as per the proposal prepared by their Deptt. DC, Goa informed that testing Laboratory is a part of the activity covered under the condition of licence for manufacturing of drugs for sale and any violation of the licensing condition, the action may be taken against the firm including the testing lab. Since the draft proposal made by DC Delhi requires amendments under the Act, the chairman requested DC Delhi to modify the draft proposal in such a way so that it may be required to	DC (Delhi) was requested to forward the draft proposal for consideration. Draft proposal has since been received and placed for consideration and discussion.

		amend only the rules, in order to regulate the approved testing Laboratory.	
9.	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, 27-D and in Rules 27, 75(A), 76, 79(A), 65(2) and 66 of the Drugs and Cosmetics Rules.	The Commissioner, FDA, 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 titile of the Agenda. For this purpose, he brought certain write-ups on 22.9.1998 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.	Report of Expert Standing Committee was circulated to member for comments. Only DC (Delhi) has forwarded comments, which is for consideration and discussion.
SPECIAL DCC			
iii)	Action taken on the recommendation of Hon'ble NHRC order dated 31/3/99 vide item no. (iii) regarding uniformity of formats for GMP. non-conviction, free	Report of group of State Drugs Controller on uniformity of formats for GMP, non conviction, free sale certificate etc. was circulated to members for comments.	Comments received from DC (Delhi) was circulated to members for seeking comments in time bound manner. Since no comments have been received, a final view in the matter may be taken, being an NHRC issues. A copy of revised format is for consideration

	sale certificate etc.		and discussion.
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.	Report of the Expert committee under the chairmanship of DC (WB) may be finalized after seeking comments from the members.	Having obtained comments, report of the expert committee along with the proposed check list/guidelines for auditing the Medical store has been finalized and circulated to all members for compliance etc.
10.	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.	DCC recommended to get the proposal examined through sub-committee. Report of the sub-committee has now been received and placed for consideration.
11.	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.	It was decided that members would furnish the factual position/status report on recycling of used disposable syringes/needles existed in their state. Status report received from Drugs Controller Delhi, Mumbai, Haryana, Gujarat and Karnataka is placed for consideration.

		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.	

12.	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.	Members agreed with the proposal. However, DC (Delhi) was requested to seek the opinion of few anaesthologists using 93% oxygen from the angle of safety aspects. Opinion of Anaesthologist on safe use of 93% is placed for consideration it may also be discussed to identify the Laboratory for testing of Medicinal Oxygen in case of complaint as the CDL/CIPL do not have such facilities.

		hospitals to be used for hospital patients under prescribed conditions.	
13.	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.	DC (Karnataka) and the Comm. FDA Mumbai were requested to examine and convey their views. Comments of Comm. FDA Mumbai, has now been received and is placed for consideration.
14.	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.	DCC recommended to get the proposal examined through sub-committee under the chairmanship of Commissioner, FDA Maharashtra. The sub-committee could not meet. However, this Directorate has formulated a proposal, which is placed for consideration. Proposal need to be further discussed so as to frame GMP guidelines and testing procedures etc.

Supplementary Agenda items			
15.	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	Members were requested to furnish their comments. No comments received. However, an amendment has been made in schedule 'K' after Sr.No. 5(a) with regard to exemption to be provided for whole human blood I.P. and/or its components stored for transfusion by a First Referral Unit, Community Health Centre, Primary Health Centre and a Hospital, which is placed for consideration.

		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.	
State Agenda			
16.	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.	It was decided that the proposal be examined through sub-committee under the chairmanship of the Commissioner, FDA (MS). Report of the sub-committee has since been received and is placed for consideration.
17.	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	DC (GOA) was requested to furnish the detailed proposal for further examination of the committee. Detailed proposal has now been received and being kept as state agenda for discussion. Refer to (Agenda Item No. 33).

		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.	
18.	Consideration for prescribing uniform limit regarding net content of liquid oral	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.	DCC requested to Director CIPL Ghaziabad to examine and suggest suitable corrective measure. Views of Director CIPL, not received.
19.	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	DCC referred the proposal in respect of rubber and dotted condoms and limit of preservative in ophthalmic preparations to Director CIPL Ghaziabad for examination and comments. Views of Director CIPL, not received.

		necessary examination.	
20.	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.	It was decided that DC (Karnataka) would furnish draft protocol for drawing sample of blood. Draft protocol, not received.
21.	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.	DCC recommended to get the proposal examined through sub-committee under the chairmanship of DC (Kerala). Sub-committee could not meet. However an amendment has been made in schedule 'K' after Sl. No. 5(a) with regard to exemption to be provided for whole human blood I.P. and/or its components stored for transfusion by a First Referral Unit, Community Health Centre, Primary Health Centre and a Hospital. The Amendment is placed for consideration.
22.	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	Members agreed to include Buprenorphine hydrochloride under Schedule X to the Drugs & Cosmetics Act. However opinion of few renowned clinician experienced with this Drugs should be obtained. Opinion of

		under Schedule 'X'. However, opinon of few renowned clinicians experienced in using this drug may also be obtained.	renowned clinician is placed for consideration. Further in a study conducted by M/s. Unichem Labs., on abuse potential of Buprenorphine at three different centre it was observed that out of total addictive patients only 10% reported to be abused with Buprenorphine and remaining 1/3 and 8.6% were reported to be addicted with Benzodiazepine group and opium derivatives respectively.