MINUTES OF THE 35th MEETING OF THE DRUGS CONSULTATIVE COMMITTEE HELD ON 29th & 30th APRIL, 2004

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Minutes of the 35th Drugs Consultative Committee Held on 29th & 30th April, 2004 at Nirman Bhawan, New Delhi

A. **CONFIRMATION OF THE MINUTES OF THE 34TH DCC MEETING HELD ON 8TH & 9TH APRIL, 2002.**

The committee unanimously agreed to the minutes of the 34th DCC meeting held on 8th & 9th April, 2002.

B. **CONSIDERATION OF THE ACTION TAKEN REPORTS ON THE SUPPLIMENTARY AGENDA RELATED TO EARLIER DCC MEETINGS**

Supplementary agenda related to 32nd DCC meeting

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, the Commissioner FDA, Maharashtra informed the members that the private testing labs can be prosecuted under IPC, if there is culpable offence on the part of the licensee. Since Drugs and Cosmetics Act & Rules thereunder is also read with IPC, therefore, approved testing labs can be booked under IPC. There are otherwise adequate provisions to withdraw the approval.

It was explained by the chairman that issues concerning Drug Testing Laboratories have been deliberated by Mashelkar Committee. The recommendation of committee would need a closer look by DCC, for which there is a specific agenda for discussion. It would, therefore, be appropriate to examine the issue in a comprehensive way, by the DCC.

Agenda related to 33rd DCC meeting

Item No. 1: Regulatory control on Medical Devices.

The member secretary of the subcommittee informed the DCC that ISO standards/formats are available with the subcommittee and report is likely to be finalized within 4 weeks time on the line of the decision taken in the 33rd DCC meeting. The report is at par with the current recommendations of the Mashelkar Committee. It was, however, informed by the chairman that the issue of medical devices would need to be examined in a comprehensive manner in the light of recommendations of Mashelkar Committee. This issue has been brought before DCC, vide item No. 4 (para 11 at p. 15) of the agenda items. It is proposed to constitute a separate multidisciplinary committee in consultation with DGHS for this purpose. This committee would also examine the view of DCC subcommittee on medical devices so that the scope of regulation over medicinal devices gets properly defined.

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

Director CIPL informed the members that the testing of samples of medicinal oxygen requires gas chromatography and other testing instruments and the test can be performed according to the standards prescribed in the monograph of the pharmacopoeias. While deliberating on the sampling procedure of medicinal oxygen, the members informed the

chairman that in many hospitals, the medicinal oxygen is produced by oxygen extractor plant and as such it is difficult to draw the sample of medicinal oxygen. Moreover, the oxygen cylinder manufacturers already hold ISO certification as well as manufacturing licence under the Drugs and Cosmetics Rules, 1945.

After discussion, the committee agreed that no sampling procedure could be adopted in light of the current logistic problems. However, office of DCG(I) would further examine the possible logistics in consultation with the industry and laboratories.

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 minutes of the subcommittee on standards for diagnostic kits and reagents, and separate schedule for prescribing plant and machinery required for manufacture of such kits and reagents was circulated to the members. It was decided that members would furnish their views/comments within one month time, failing which it would be presumed that members are in agreement with the recommendations of the subcommittee.

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

Since the use of preservatives in ophthalmic preparations does not require any expert committee to resolve this small issue, the chairman advised Director, CIPL that the limit of preservatives in the ophthalmic preparations may be examined on the basis of references already available in various reputed medical/pharmaceutical literature and also the practice adopted by the various manufacturing companies about the preservatives in the ophthalmic preparations. Report in this regard may be separately furnished to the office of DCG(I).

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

The minutes of the subcommittee was circulated to the members. While making deliberations on the report of the chairman of subcommittee, DC Karnataka, Dr. Suresh K. Mohammed, stated that sterility tests cannot be performed in the microbiology lab.

After discussion, the chairman informed the members that while accepting the guidelines, experience in other countries is required to be evaluated. Accordingly, the members were requested to furnish their

comments/views within one month time, failing which, it would be presumed that members are in agreement with the recommendations of the subcommittee in principle.

Item No. 41: **Dextropropoxephene, ephedrine hydrochloride, amphetamine, buprenorphine hydrochloride should come under Schedule X licence.**

The member secretary, Sh. SD Vijayaraghavan, ADC(I) [H.Q.] informed that report of the subcommittee on this proposal could not be managed and would be available within 6 months time. Accordingly, the DCC granted the extension time for finalizing the report.

Agenda related to 34th DCC meeting:

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.**

The report of the subcommittee recommended certain changes to be incorporated under Schedule P in line with the standards stipulated in the I.P. and also the general guidelines like framing of SOPs and stability testing of drugs etc. Accordingly, the members agreed to go through the report of the subcommittee in the context of preparing SOPs and general guidelines of stability testing of drugs for prescribing shelf life etc. and furnish their views within one month time so that a common guideline can be framed and same could be followed uniformly.

Item No. 8: **Sale of drugs including narcotic and psychotropic substances through internet.**

The committee noted that sale of drugs through internet is negligible in the country. Therefore, amending the Rules at this stage is not considered necessary. Accordingly, the DCC decided not to pursue the proposal.

Item No. 13:**Proposal to prescribe forms in which licence to manufacture ethyleneoxide gas for sterilization be considered.**

The Commissioner FDA, Maharashtra informed the committee that permission for manufacturing ethylene oxide gas for sterilization has already been issued in Forms 25,28,32 and 25D etc. So the same could be followed up by the state licensing authorities. The Commissioner FDA, Maharashtra have informed that under Schedule M-III, requirements of factory premises for manufacture of medical devices has been stipulated vide papa 6 (*Sterilization: The licensee shall provide requisite equipments with required controls and recording devices for sterilization of medicinal*

devices by ethylene oxide in his own premises or may make arrangement with some institution approved by the licensing authority for sterilization....). Since the standards of ethylene oxide gas are already available in I.P., license in Forms 25,28,32 and 25D etc. may be duly issued by SLAs. In the absence of any status paper regarding the format in which licence to be issued, the chairman agreed to get it examined by his office.

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

The chairman informed the members that WHO GMP certificate for surgical dressings does not appear to be feasible as there are no specific WHO guidelines for surgical dressings. As regards to the WHO GMP guidelines in respect of homoeopathic/herbal medicines is concerned, the DDC(I) [WZ] informed the members that there is no WHO GMP guideline for homoeopathic medicines. However, the WHO has prescribed certain norms/guidelines for herbal medicines. The chairman requested DDC(I) [WZ] to circulate the WHO guidelines to all SLAs under intimation to this Directorate so that GMP guidelines for herbal medicines could be followed uniformly and the norms are also disseminated to the concerned industry.

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

The chairman informed the committee that revised Schedule M is being further reviewed to address the problem of poultry vaccines etc. The DCC agreed with the proposal to give discretionary power to authorities concerned to relax the provisions of Schedule M in respect of poultry vaccines, which have a much different production procedure. However, the DCC was of unanimous view that Govt. units need to come up to the same standard as are expected from any private enterprise.

Item No.18: Proposal to consider relaxation clause in respect of testing laboratories under Schedule F to the Drugs and Cosmetics Act.

The report of the subcommittee was circulated to all members and the chairman requested the members to furnish their comments/views within two months time failing which it would be presumed that members are in agreement with the recommendations of the subcommittee.

Item No.24: Clarification regarding duties of inspectors prescribed under Rule 51 & 52.

The DC Karnataka informed the chairman that as per the HC order, prosecution permission has to be obtained from higher authority. This view was also endorsed by DC Kerala and DC WB. The Commissioner, FDA Mumbai apprised the members that legal procedures are well established for launching the prosecution in respect of cognizable and non-cognizable offences and one has to seek permission from the higher authority (controlling authority) before launching the prosecution. On the contrary, the DC AP informed that recently Hon'ble HC, AP upheld the decision that the Drugs Inspector need not take the permission of the controlling authority to launch a prosecution as stipulated under Rule 51 and 52. Accordingly, it was decided that DC AP would furnish a copy of the judgement of the Hon'ble HC, AP to the chairman and same would be examined by the subcommittee of DCC on legal issues.

Item No.30:Consideration of question to lay down Good Laboratory Practices under the Drugs and Cosmetics Rules, 1945.

The report of the subcommittee was not available. It was, however, informed that the working of Drugs Testing Lab requires a thorough review in the light of outcome of technical audits and the views expressed by Mashelkar Committee in the report submitted to the Govt. in November 2003. Copy of the report had already been circulated to all members. This issue has been brought before DCC vide item No. 4 (para 4.7). DCC was of unanimous view that the technical audits have revealed gross deficiencies in the overall working of labs, over which Govt. is spending so much money.

It was decided that the issue should be got examined through a laboratory subcommittee. The subcommittee would examine the issue from the angle of accreditation of labs, proficiency in testing, policy issues/training modules, quality related issues, staffing pattern, quantum of samples to be tested, framing of SOPs, motivational factors, GLP compliance, legal issues etc.

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, for the unit which has obtained the clearance from Drugs Controller General (India).

The comments provided by the office of DCG(I) were noted that separate approval would have to be obtained.

Item No. 33: Consideration of the question whether toilet soaps with the label 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.

The chairman informed the members that the matter is being pursued with Department of ISM & H (AYUSH) and as and when the comments are received, the same would be informed to the members. It was also decided to take up this matter with Indian Soap and Toiletries Manufacturers Association (ISTMA).

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

The chairman informed the members that this issue has already been considered in the Mashelkar Committee report, which has recommended for compounding of offences and amending the Act for this purpose. Various recommendations of the Mashelkar committee pertaining to regulatory issues are to be examined by DCC including compounding of offences and penal actions etc. A specific agenda has, therefore, been proposed for detailed discussion on Mashelkar committee recommendations.

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

The committee was informed about the proposal to amend the revised Schedule M so as to provide for discretion clause is under consideration of Govt. DTAB has already recommended for it.

Item No. 42: **Manufacture of nutraceuticals, cosmetics, ayurvedic etc. in the licensed premises.**

The clarification provided in the agenda note was accepted by the committee. It was further informed that the proposal is presently under consideration of Govt.

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

No consensus could be arrived on this issue. Since DC Karnataka raised the issue, the chairman requested DC Karnataka to have a fresh look on this issue and convey his comments to the DCG(I) after consulting their Law Department.

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

While considering the report submitted by CDL, Kolkata about the quantity of samples to be sent for test/analysis, various members of DCC expressed their difficulties in sending the drug samples as per the quantity fixed by the CDL, Kolkata. Many members suggested that sending the samples as a practice depends on type of sample, type of the test to be performed, and the availability of similar batch number etc.

Accordingly, the chairman advised the members that the practice earlier adopted for sending the samples to CDL, Kolkata will be in existence keeping in view the present list as a model guideline. It was also decided that this issue may also be examined by the DCC subcommittee, which would be constituted to look into all laboratory related issues.

C. Central Agenda Items

Item No. 1: Training programme of drug regulatory staff under World Bank assisted Capacity Building Project.

The Joint Secretary, Ministry of Health & Family Welfare, Mrs Rita Teotia, explained the overall objective of the training programme for drug regulatory staff under World Bank assisted Capacity Building Project. She encouraged the regulatory staff to participate in this training programme with great involvement. The training programme can be modified depending on the feedback from trainees and specific needs felt by the Drugs Controllers. The training programme would also cover the middle level and senior drug enforcement staff, analysts and the production and quality control personnel from the industry especially from the Small Scale sector. She further informed the members that training programme has commenced at National Institute of Pharmaceutical Education & Research (NIPER), Chandigarh and training plan and training modules have been prepared. As per the training plan, 2600 personnel would be trained by the end of the project period and a significant part of this would be from the private sector. In addition, 10 national seminars and 10 workshops would also be organized during the project to discuss the key policy issues on drug quality.

Given the background performance of the training programme, she informed that first programme of the series was successfully completed covering a period of 12 days from 19/1/04 to 30/1/04. This programme was attended by Drug Regulatory Officials in the rank of Assistant Drug Controller, Senior Drug Inspectors and Drug Inspectors. The performance of this programme was rated as high. The second programme was started in February, 2004, which was attended by 42 personnel from the Small Scale Industry. More training programmes are in the offing.

The chairman requested Dr. Kaul, Director, NIPER to address the members of DCC and to throw light on the various training modules piloted by the NIPER. Dr. Kaul in his address, informed the members that the training programme is planned for the total coverage of five years. Each training module has been designed keeping in the perspective of current drug regulatory affairs, quality control, manufacturing, validation techniques, total quality management etc. Many training modules have been designed as short-term courses. The modules have been designed according to the hierarchy level of the drug regulatory staff. The voluminous course material shall be distributed before or after completion of the training. There shall be no fees or charges towards the training programme. As of now, 3 programmes have been undertaken by the NIPER. It was, however, observed that many States are not nominating their staff in time for getting the full benefit of the training programme. Taking advantages of the opportunities provided by the training programme it would help immensely in improving the quality and uniformity of enforcement in the country.

After the remarks of Dr. Kaul, the chairman requested the members to exchange their notes on this issue so as to get maximum benefit of the training programme. DC Bihar suggested to Dr. Kaul that the details of the training programme should come one month in advance so that member could be nominated from the State. Being an administrative procedure, the approval of their Health Ministry is to be obtained for the nomination. The DC Rajasthan asked Dr. Kaul whether TA/DA shall be given by the NIPER. Dr. Kaul clarified that TA/DA is being given to the Govt. persons presently, but may also be extended to industry personnel.

Summing up, Joint Secretary (H) informed the members that annual calendar of the training programme is already attached with the agenda and requested members to plan in advance to ensure that training programme is attended by their staff. The DCG(I) also requested members to participate in the training programme with keen interest and also to contribute for its improvement. It needs to be appreciated that it is a unique initiative taken by the Govt. of India and is a valuable opportunity for regulatory staff for skill improvement, as well as to interact with their collegues from other States. This would definitely pave the way to bring in much closed uniformity of enforcement in the country. DCC members appreciated the efforts put in by CDSCO and Ministry of Health & Family Welfare in conceptualizing planning and executing the new initiatives in the country.

Item No. 2: World Bank Assisted Capacity Building Project on Quality Control of Drugs – Preparatory Activities.

Joint Secretary (Health) initiated discussion on the issue. It was explained that under the project we plan to develop infrastructure both under Food and Drugs by setting up new laboratories and renovation and extension in the existing laboratories, provision for equipment, furniture, material and supplies, incremental staff and training to upgrade their skills. The Project costs, under Central and State Sectors separately for Drugs, has been shown in the agenda note.

The main components of the Project are as below:

- Achieving uniform GMP and GLP and better enforcement of the Drugs & Cosmetics Act and Rules uniformly throughout the country.
- Enhancing testing capacity in the Govt. Labs coupled with audit of the private drug testing laboratories
- Imparting training in enforcement of Drugs & Cosmetics Act and Rules and consequent improvement in skills of regulatory staff, Govt. Analysts, quality control analysts and manufacturing chemists of the small scale drug industry, and training of trainers.
- Benefiting consumer through improved assurance of quality of drug formulations manufactured in and imported into the country and provide required confidence among health care providers as well as consumers about quality of generic drugs manufactured by large number of drug manufacturing units in the country.
- Establishing an appropriate infrastructure for new drug approval to match global safety, efficacy and rationality standards.
- Strengthening surveillance systems for adverse drug events.
- IEC Activities in a systematic manner to raise awareness related to use of drugs.
- Indian Pharmacopoeia Commission will be setup for preparation, publication and distribution of Indian Pharmacopoeia, The National Formulary of India and periodical up gradation of the standards. The Indian Pharmacopoeia Commission would undertake preparation and distribution of reference standards of drugs.

The agenda note provides the details of logistics and road map for implementation of the project. In order to ensure timely and adequate preparations for implementation of the project, it is essential that preparatory actions be completed well in time. It is most critical that the concerned States complete the preparatory activities as detailed below:

1. In case of Civil Works, it should be ensured that adequate land is available with clear title and there is no encroachment, layout plan and detailed drawings are available for the labs, where renovations/extensions have been planned.

2. The Drug Laboratories, which are being strengthened under the project way of laboratory equipment, should ensure availability of space with electric connection, adequacy for the requirement for equipment, availability of personnel for operation of equipments.

3. Specification for furniture being provided under the project for laboratories should be got approved from the competent authority and it should also be ensured that there is adequate space for keeping the furniture.

4. The laboratory should ensure that technical specifications have been approved for each item of Chemicals. Requirements have been worked out on realistic basis, before procurement against the Price Contract and that there is adequate record keeping in place for the chemicals received.

5. Steps have been taken for contractual staff, which will be appointed on year-to-year basis.

6. In case of incremental staff on regular basis, job description, minimum qualification, terms of appointment and selection procedures have been finalized and the posts have been sanctioned by the Government.

It was strongly stressed that well coordinated activities between State organizations, HSCC, and the project implementation cell at Centre would be essential for efficient and timely execution of the project.

Item No. 3 : Computerization programme.

Discussion on computerization programme was initiated by the DCG (I). Representatives of HSCC participated in the discussion and gave a detailed account of the progress so far made and its present position. Joint. Secretary (Health), Mrs. Rita Teotia, advised the State Drug Controllers to expedite all necessary formalities for installation of hardware and to complete the data entry.

A serious concern was expressed about the fact that in some states, the installation is getting delayed and the executing firm is being called again and again due to minor impediments. It was informed by members that the hardware has been made available. However, the UPS supplied by the

firm is giving trouble as it frequently breaks down. Jt. Secretary (H), advised HSCC to take a serious note and have the UPS replaced. It was decided that HSCC would keep in active touch with the office of DCG (I) to make sure that there is smooth functioning at every state level office and laboratories.

It was pointed out by few states that their manufacturing licensing activities is also delegated to divisional hqrs. However, the present programme is limited to State Hqrs. HSCC was requested to look into it and suggest feasibility of further downward linkage. For further connectivity, the concerned states were also advised to examine possibility of additional fund from within their budget. A need was also expressed about some improvements in the software in order to make it more user-friendly. HSCC was requested to arrange for a meeting of few state representatives and CDSCO to look into all remaining issues about the software and sort them out at the earliest.

Summing up the discussion, the Chairman requested all members to give a serious attention to the logistics and ensure speedy implementation of the computerization programme.

Item No. 4 : Mashelkar Committee's recommendations.

The Chairman explained in detail, the genesis of formation of Mashelkar Committee by Govt. of India. It was pointed out that a copy of report has already been circulated to all State Govts.

The Committee expressed the view that the report of Mashelkar committee would prove to be an important milestone in the progress of drug regulatory system in the country. It has articulated on various areas of drug regulatory activities, which have direct impact on the competence, and preparedness of drug regulatory agencies in the country. Issues like lack of uniformity of enforcement in respect of infrastructure, and skills of enforcement staff, emerging regulatory challenges, regulations over related health care products, the global drug regulatory scenario etc. have been deliberated by the committee and number of recommendations and suggestions have been made in its report submitted to Govt. in November 2003.

The Chairman informed the DCC that as far as Committee's recommendations for enhancement of penalties under Section 27 of the Act and the provisions for compounding of offence are concerned, the Govt. introduced a bill in the December session of 13th Lok Sabha.

Since the report has recommended on large numbers of issues concerning functioning of drug testing laboratories, medical devices, drug distribution

pattern, good regulatory practices, uniformity of enforcement modalities, level playing field for pharma industry in the country etc., it was decided that DCC should undertake a serious examination of individual areas and come out with appropriate suggestions for their implementation. The members expressed their appreciation about the way the committee has covered large number of areas which have a direct or indirect interface with the drug regulatory functions in the country and to bench mark it with the international standards.

After detailed deliberation on the specific recommendation as brought out through various paras in agenda item no. 4, it was decided as follows :-

Para 2.9 (i) and Para 2.9 (ii):

Para 2.9(i): **Guidelines and directions issued to the State/UT Drug Regulatory Authorities on regulatory policies should be strictly and uniformly complied with failing which action may be taken against the concerned regulatory officials;**

Para 2.9 (ii): **Based on the accepted performance indicators of a good regulatory agency, the functioning of drug control agencies may be audited by a panel of independent experts. This activity should be funded by the central government. If the performance of any state DRA is found to be below par and/or not in accordance with the provisions of the Act and the Rules, the Central government shall have the powers to take suitable action.**

Members agreed that in order to ensure uniformity, there is a need of stricter self regulation and some mechanism to monitor the same. Since DCC has a major obligation in this regard, the issues would require an extensive examination by a core group. Some of the members specifically pointed out the problem of granting approval of drug products by some State authorities, which are otherwise to be considered as new drugs as per the overall definition under Rule 122E. They requested the chairman to take a strong note about such blatant deviation. It was explained by the chairman that in a public interest litigation (PIL) filed in Delhi High Court, the Govt. had explained through affidavit that in May, 2002, the Rules have been amended so as to rule out such possibility. The court had noted this fact in their judgment delivered recently. It is, therefore, unfortunate that some States/U.Ts. have ignored even the amended Rules.

The members, agreed that in case such permissions have been granted, the same would be suspended and the concerned manufacturer would be advised to approach the office of DCG(I) to seek clearance as per the prescribed procedure. It was also decided to refer the matter to DCC subcommittee for suggesting suitable remedial measures.

These suggestions of Mashelkar Committee report could, therefore, be examined by the sub committee of DCC on enforcement issues. The sub committee would provide specific guidelines and modalities etc. within three months.

Para 2.10(i): The Drugs and Cosmetics Rules provide that the manufacturers as well as wholesalers and retailers have to obtain separate licenses based on categorization of drugs classified as C & C1 and those other than C & C1. These provisions have been in place since inception and they need to be reviewed to further rationalize the licensing and regulatory procedures keeping with the contemporary developments.

This issue concerning clubbing of Schedule C and C1, and other than C and C1, drugs etc. would be articulated by subcommittee on legal matters. At least for sale of drugs, such a clubbing may not have any difficulty. However, for manufacturing areas of drug, a new category wise approach may be considered as against the existing framework.

Para 2.10. (ii): Section 33 P of Drugs and Cosmetics Act may be amended to give powers to DCG(I) to issue directives to state licensing authorities, to review the orders passed by them and if necessary, to revoke the product permission granted by them.

This is a serious issue and was even suggested by some state drug controllers who rare seriously concerned about the criticism expressed at various fora about non uniformity of implementation of various guidelines and decision in the county. It was decided that the sub committee on legal matter would suggest appropriate modalities in this regard as to how to tackle these issues in respect of states who deviate from accepted norms.

Para 2.11: The Committee recommends that the State Drug Control Organisations should be urgently strengthened with competent and trained manpower and with adequate budgets. Structured mechanisms should be set-up to enable interstate exchange of regulatory officials to bring about better understanding of processes adopted in different states. This would help in harmonising the enforcement practices and would bring an improved uniformity.

The recommendations found favor from most of the members. It was agreed that while drug testing capacities would be strengthened under capacity building project and a fair level of upgradation of skills of regulatory personnel would also be enabled under the project, the actual requirements of enforcement staff, intelligence cell etc. would have to be separately worked out by State organizations. Interstate exchange of

regulatory personnel is a good suggestion. The DCC subcommittee on enforcement may further examine the issues related to it.

Para 2.12: **The specific actions recommended for State Drug Control Organizations are as follows:**

a. **Strengthen the State Drug Control Organization with additional manpower, infrastructure, technical capabilities and financial sources.**

b. **Set up Intelligence cum legal cell under the supervision of trained senior nodal officers. The State Government should put in place efficient mechanism for timely police help to these officers.**

c. **Establish a proper surveillance system for keeping a watch over suspected persons. Watchers should be employed and secret funds may be made available for intelligence activities.**

d. **Set up efficient communication networking for sharing and exchanging information in cases involving inter-state movement of spurious drugs.**

e. **Request the government to identify designated courts for speedy trial of spurious drug cases.**

f. **Set up an adequate testing laboratory according to the need to ensure that the suspected samples are tested expeditiously.**

g. **Monitor the sources of purchase and quality of drugs stocked by dispensing medical practitioners and institutions.**

h. **Provide a toll free number to receive public complaints/ information, etc.**

i. **The condition of license for sale of drugs should be strictly enforced.**

The Chairman explained that these recommendations pertain to logistics of an efficient enforcement and surveillance system to check movement of spurious or any dubious quality drugs in a state as well as in interstate commerce. Similar recommendations/ suggestions have earlier been conveyed to state organizations and were also discussed in the meeting of Central Council of Health & Family Welfare (CCH &FW). All Chief Ministers had also been requested to ensure that adequate measures are taken by state drug control organization. The Mashelkar Committee has however, also highlighted the need for monitoring the drugs supplied to medical practitioners and to hospitals It is for the state Govt. to make

serious attempts in this direction. Members took note of the recommendations.

Para 3.3.3 {of Para 3.3: Over The Counter Drugs (OTC)}: **A mechanism should be set up to review the list on a periodical basis. This should enable bringing in sufficient flexibility in the system on one hand and promoting sales and distribution of desirable products without in any way compromising on quality of the product on the other hand.**

The Chairman explained that this issue was earlier examined by a subcommittee of DCC and is now under consideration of DTAB. A policy guideline is also being framed by which firms can petition for shifting a drug from prescription status (Schedule H) to a general sales or even non-pharmacy status.

Para 3.6 : **Storage and Distribution.**

a. **Para 3.6.1: State Licensing Authorities should devise suitable standard operating procedures to restrict excessive concentration of retail/wholesale outlets.**

b. **Para 3.6.2: The drug manufacturers should follow good storage practices for their products during transport as well as their depots.**

c. **Para 3.6.3: The drug manufacturers should have limited number of main stockiest. Only these main stockiest should sell to the retailers or hospitals.**

d. **Para 3.6.4: The manufacturers should ensure that retail and wholesale chemists are aware of proper storage conditions of their products.**

Members were unanimously of view to provide for some suitable mechanism to avoid mushroom growth of sales outlets. A sub Committee under the chairmanship of Commissioner FDA, Gujarat is examining this issue. However, being a complex issue, it has not been possible to decide the matter. The proposed DCC subcommittee on enforcement may take a final view in the matter. View of trade association may also be obtained by the subcommittee. It was decided that some of the issues related to industry would be taken up with industry associations.

Para 4.3 : **The gist of the recommendations to tackle the spurious drugs problem is as follows:**

a. **Creation of effective interaction between the stakeholders i.e. industry and regulators, industry and consumers, trade and regulators and medical professional and regulators.**

b. **Creation of intelligence cum legal cells in State and Central offices.**

c. **Discouragement of proliferation of drug distribution outlets.**

d. **Making changes in law to provide enhanced penalties, making the offences cognisable and non-bailable in the light of similar provisions in Narcotic Drugs and Psychotropic Substances Act.**

e. **Designation of special courts to try the cases of spurious drugs.**

f. **Preparation of dossiers of suspected dealers and manufactures.**

g. **Provision of secret funds and incentives to informers.**

h. **Creating effective networking system between States**

i. **Checking on drug supplies to practitioners who buy and supply drugs to their patients.**

j. **Creation by the industry of its counterfeit drug strategies, better surveillance and efficient complaint handling system.**

k. **Creation of better surveillance system by the Trade Association on defaulting members and to take strict action against them.**

l. **Creation of better awareness amongst consumers.**

The member of DCC noted the recommendation of Mashelkar Committee in respect of measures required to tackle the problem of spurious drugs. Many members explained that over the years, various measures as identified by the Mashelkar Committee have already been initiated in their states. However, if uniformly serious attempts are made by all states, a greater success can be achieved. It was agreed that this is a continuing activity and all possible measures, which would help in improving the monitoring and surveillance system, need to be taken. The activities taken up under Capacity Building Project, commissioned by Central Govt. including proposed IEC activities can be taken help of in this direction.

Para 4.4 : **The Committee noted that there is non-uniformity in the action taken on substandard drugs, especially when the manufacturer of substandard drugs is located in a different state. The Committee recommends that:**

- **The DCC should deliberate on the issue of action to be taken on substandard drugs and review the existing guidelines. It should analyse the nature of substandard reports and status of concerned manufacturing units as well as the system of distribution; and**

- **The existing classification by DCC of defects found in substandard drugs into category A and category B and the action to be taken on each category of defects needs to be reviewed and updated.**

The members agreed to the suggestion for review of existing guidelines on the action to be taken on not of standards quality drugs through the sub committee on enforcement matters.

Para 4.7 : **As regards the improvement of the drug testing laboratories, the committee recommends the following:**

- **Para 4.7 (b): Accreditation with NABL should be made mandatory for all testing laboratories including the Government laboratories.**

- **Para 4.7 (c): The Central Government should initiate a programme to have coded samples of the same product tested at different central and state labs from time to time and have the results assessed by experts for their proficiency testing.**

- **Para 4.7 (d): The state testing labs should be frequently audited by a team of experts to ensure their proper functioning.**

- **Para 4.7 (e): A separate Division needs to be established under CDA to oversee the overall working of drug testing laboratories in the country.**

The Chairman informed the members that proper attention needs to be given to the functioning of drug testing laboratories, which are pivotal to ensure efficient monitoring of drug quality. This is a professional activity, which requires high degree of self-regulation, constant improvement and adherence to the principles of good laboratory practices. Unfortunately, as revealed by the technical audit exercise undertaken by Central Govt., all is not well. What disturbs is the slow pace of compliance inspite of repeated requests to concerned States and incharge of laboratories.

The Mashelkar Committee recommendations in regard to drug laboratories were considered to be very pertinent by the members. It was decided that a proper strategy and road map should be drawn by the laboratory personnel themselves. There is also a suggestion to give statutory shape to the requirements of GLP. It was therefore, agreed to constitute a separate Sub Committee of DCC to examine all earlier recommendation and the present suggestion of Mashelkar Committee for improving the functioning and work culture of Govt. drug testing labs. in the country in a time bound manner. The committee may if required even visit some state or central labs for first hand assessment of the issues.

In the meantime, the incharge of all laboratories should ensure that all technical staff of their laboratories is aware of the concept and requirements of GLP. They should also initiate there own internal audits and performance evaluation of the chemists.

Para 3.5 : **Medical Devices and Diagnostics.**

- **The 'Medical Devices' should be specifically defined under section 3 of the Drugs and Cosmetics Act and relevant Rules and guidelines framed for their proper regulation.**

- **A specific Medical Devices Division should be set-up in the office of newly restructured CDA for proper management of approval, certification and quality of medical devices.**

- **An appropriate regulatory mechanism should be set up by CDA for certification, quality assurance and post-marketing surveillance of imported as well as locally made medical devices.**

DCC may examine the above recommendations so as to formulate appropriate guidelines or suggestions for further follow-up action.

The Committee unanimously agreed to the need for revamping the existing provisions concerning medical devices and diagnostics and to create a dedicated division at central level to oversee regulatory functions over these health care products. It was also agreed that the present mechanism of notifying devices as drugs under Section 3 (b) needs a change. Members requested the Chairman to constitute a multidisciplinary sub committee for this purpose. Two members of the Committee may be drawn from the DCC members having reasonable activity of medical devices/diagnostics manufacturing in their states.

Item No. 5 : **Guidelines for inspection of drug manufacturing units and Standard Operating Procedures.**

Concern has been expressed at various fora about lack of uniformity in enforcement of the provisions of Drugs and Cosmetics Rules as amended from time to time and various guidelines issued in this regard. It has been observed that there is no uniform pattern for inspection of drug manufacturing units and Standard Operating Procedures followed for such inspections as well as the follow up actions. The regulatory agencies are required to have a proper quality system in their working and to ensure a level playing to the industry. The rule has provided specific provisions for duties of inspectors especially authorized to inspect drugs and cosmetics (Rule 52).

It is, therefore, felt that standard inspection formats/protocols may be prescribed for inspection of drug manufacturing establishments covering different dosage forms etc., which would be followed regularly by the respective inspection authorities of all State Drug

Control Organizations/CDSCO including the norms for sampling of drugs and cosmetics.

DCC may deliberate on this issue to frame appropriate guidelines.

Considering the serious need of uniformity in the enforcement of the provisions of Drugs & Cosmetics Rules in the country, and various guidelines issued from time to time, the Chairman informed the members that a uniform pattern for the inspection of the Drugs Manufacturing Units and the SOPs followed for such inspections as well as follow up action should be developed. There is often criticism about inadequate inspection and audits of GMPs or an element of subjectivity in inspection even within a State. The rules have already been provided for duties of inspectors. It is, therefore, felt necessary to make SOPs for the inspection of Drug Manufacturing Establishments, which would be followed uniformly by the State Licensing Authorities. While on discussions, the Chairman further informed that in case of vaccines and sera, a basic WHO checklist had been circulated to all stakeholders so as to comply with the requirements as stipulated in these guidelines. It was emphasized by the chairman that all over the world, drug manufacturing is regulated by a central authority. It is, therefore, imperative that in the Indian situation, uniformity of regulatory activities would have to be ensured through a common model of instructions etc. Some members opined that NIPER could be utilized for developing SOPs/Manuals, which could be followed uniformly. Few members suggested that the inspection proforma/SOPs should be according to section-wise/dosage-wise. It was agreed by the members that uniformity of the enforcement is also essential as level playing field is to be provided to the industry in the country.

Considering the viewpoints, the members suggested that a sub-committee should be constituted to devise the inspection manuals/SOPs to be followed by the State Drugs Controllers at the time of inspection. Inspection profroma should be designed according to dosage forms except for vaccines/sera. The sub-committee may also incorporate representatives from manufacturing association, if required and should also look into available modules. The group would also look into WHO guidelines for inspections, the concepts of Drug Master File for every drug formulation etc. The committee decided to refer the matter to subcommittee on enforcement matters.

Item No. 6 : **Blood Donation Camps.**

To ensure blood safety, it should be made mandatory that blood donation camps organized by various voluntary/charitable organizations would only be allowed to those organizations who are

holding valid drug license duly approved by the Central Licensing Authority. DCC may examine and give its recommendations.

After the discussion, the members agreed that blood donation camp organized by various voluntary/charitable institutions should be allowed to those organizations, which are linked to a valid licensed Blood Bank duly approved by the Central Licensing approving authority.

Item No. 7: **Licensing of stand alone blood banks in the private sector.**

Consequent to the National Blood Policy, a draft amendment with regard to the licensing of various types of Blood Banks has been forwarded to the Ministry of Health for publication of draft notification.

The proposal is to amend the Drugs & Cosmetics Rules, 1945, in Rule 122 G, after clause (v), the following clause is proposed to be inserted , namely :- as "Application for grant and/or renewal of licence for operation of blood banks/processing of human blood components shall be made by the blood banks run by Indian Red Cross Society, Hospitals, Charitable Trusts or Voluntary Organisations approved by the State/UT Blood Transfusion Councils only.
Provided that the aforesaid provision shall not apply to the other existing blood banks holding valid licences, and complying to the conditions of the licence, before the commencement of the Drugs & Cosmetics (Amendment), Rules, 2003."

In this regard a letter was circulated to all States on 4th August (copy enclosed). The States were also informed that applications received from stand alone blood banks upto the cut off date of 13th May, 2003 only should be processed as per the provisions of the Drugs & Cosmetics Rules. It has been observed that many such stand alone blood banks are applying for licence under the guise of charitable trust. Many such applications are pending with States for want of concurrence from State Blood Transfusion Council. There is a need to deliberate the issue regarding the minimum criteria for recognizing as / defining a charitable trust so that it facilitates the State / UT Blood Transfusion Councils to recommend the licensing of such blood banks. Applications of such blood banks may not be entertained.

Members of DCC may deliberate for appropriate suggestions in the matter.

The matter was deliberated in detail. Many members expressed views that though they are advising not to file applications for purely stand alone type of blood banks, statutorily, it becomes difficult if such an application

is filed. Also some applications have been in pipeline even in respect of the May, 2003 guideline. It is, therefore, necessary that notification amending the existing rules be issued immediately. The members also wanted the explanation about charitable trusts to be reflected in the notification. It was also explained that in many States, the State Blood Transfusion Councils (SGTC) are not functioning actively. A point was also raised in regard to the status of blood banks now a days being established by professional bodies like Indian Medical Association as these are also stand alone blood banks.

It was decided that consequent to application of draft notification, which is in pipeline, the State Drugs Controllers may convey their specific views so that the final notification has abundant clarity with regard to the objective to be achieved.

Item No. 8 : Sale of Drugs without Prescription.

It has been represented by Voluntary Health Association that huge stocks of drugs like Ketamine inj., Sildenafil Citrate, Codeine Phosphate, Valium-10 etc. are being stocked and sold indiscriminately for misuse by the chemists. It has been suggested to issue instructions to all chemists and stockists not to sell such drugs for misuse without proper prescription. DCC may examine the above suggestion.

While on discussion, the Chairman informed the members that a representation had been received from voluntary health association of India about the indiscriminate use of drugs like Ketamine Injection, Sildenafil Citrate, Codeine Phosphate, Valium 10 etc. as well as heavy stocking of these drugs by the Chemists.

Drugs Controller Goa informed that Oral Jelly also being misused. Drugs Controller Rajasthan suggested that Ketamine is very old drug and its production could be checked at the manufacturer's end. Some members suggested that the distribution patterns in respect of these drugs can be monitored. Drug Controller Delhi suggested that the indiscriminate use of these drug cannot be totally avoided, however, we could regulate its sale by keeping strict vigilance on the movement of such drugs. A general awareness about the consequences of the abuse of these drugs could be helpful in combating with such situation. It was agreed that the proposed IEC activities under Capacity Building Project could address these issues. It was also agreed by the members to keep a stricter watch over possible misuse of these drugs.

Item No. 9:Proposal for consideration of guidelines for destruction of drugs, which are declared to be not of standard quality.

The Drugs and Cosmetics Act and Rules thereunder provides for destruction of sub standard drugs (Section 31 read with the Rule 58A). However, the application of this Rule relates to those drugs, which are contravening the various provisions of said Rules. Moreover, this provision relates to those drugs, which are confiscated/seized by the drugs inspectors at the time of launching the prosecution. Based on the recommendations of the earlier DCC meetings, the office of DCG(I) has also forwarded the SOPs for recall of goods which are declared to be not of standard quality to all the State Drugs Controllers and Zonal Officers of CDSCO. However, there are no clear-cut instructions regarding the manner in which the recalled goods could be reprocessed or to be destroyed.

Recently the WHO team who had visited India for NRA assessment work, has also gone through the various provisions prescribed under the Drugs and Cosmetics Rules and recommended that DCG(I) should prepare an internal document listing the requirements for destruction and notification of destruction. Also, prepare instructions and report forms for the end users to document the destruction and submit to the DCG(I) and related State Drug Organizations. Members may like to deliberate on this issue and furnish their recommendations.

It was decided that a suitable guideline and SOP in this regard would be suggested by the DCC subcommittee to be setup for looking into enforcement issues.

Item No. 10: Director IVRI proposed amendments in Indian Pharmacopoeia 1996 Vet. Supplement – 2000.

S. No	Description	Page No.	Amendments Suggested	Justification for Amendments
1.	Sterility Test: All vaccines comply with the test of sterility appendix 9.5, using method A (membrane filtration).	92	Appendix 9.5: Method A & B may be followed.	Appendix 9.5: BP Vet and 9CFR of USDA state use of membrane filtration for the products with volume more than 100ml.
2.	Sheep Pox Vaccines – Virus titer: No less than 10 $TCID_{50}$ per dose	123	Virus titer: No less than 10^3 $TCID_{50}$ per dose	Misprint in the IVP – 2000
3.	Ranikhet Disease Vaccine, Live (Mesogenic Strain) – Virus titer: Not less than 10^6 $TCID_{50}/EID_{50}$	120	Virus titer: 10^5 $TCID_{50}/EID_{50}$ per dose	Suggested titer on the basis of common consensus of poultry specialist

4.	Infectious Bursal Disease Vaccine Inactivated	114	HI test is recommended be replaced with Agar Gel immunodiffusion test	The virus is non-haemagglutinating
5.	COFAL Test	93	COFAL test to be used for master seeds only	As it is a complicated test, it may be carried out only on master seeds
6.	Inactivated vaccines for Poultry to be produced in SPF eggs		Inactivated Vaccines to be prepared in eggs from clean/healthy poultry flock free from Salmonellosis and Mycoplasmosis	In view of the inactivation of the agent to be used in the vaccine, eggs obtained from clean flocks may be used which will not adversely affect at all the quality of the vaccine
7.	Infectious Bursal Disease Vaccine, Live: Safety test is to be carried out in SPF chicks.	115	SPF chicks to be replaced with chicks having maternal antibodies	
8.	IBD Vaccine, Live Safety Test: The recommended procedure is lengthy and involves lot of histopathological work on every batch	115	The recommended test should be carried out on master seed. On commercial batches test recommended test as below: "10 field doses of the vaccine administered by eye drop to each of the 14 chicks at the age recommended by the manufacturer. No vaccinated chicks should die with symptoms of Bursal disease. Recommended period of observation should be 21 days"	Vaccine is meant for commercial chicks and is desirable to carry out test on commercial chicks.
9.	Vaccines in multiple dose containers must invariably contain a Bacteriocide	91	Bacteriocide should not be added to live vaccine while in inactivated vaccine it can be added.	Bacteriocide may affect the viability of virus.

Director, IVRI proposed certain amendments in IP 1996 Veterinary supplement along with the justifications. DCC agreed with the proposal of Director, IVRI. Matter be referred to Director, CIPL for making addendum in this regard.

Item No. 11: Director IVRI Proposed Amendment in Rule 71 (4A) of the Drugs and Cosmetics Act, 1940.

As per the Rule 71 [(4A)], the Head of the testing unit shall possesses a degree in Medicine or Science or Pharmacy or Pharmaceutical Chemistry of a University recognized for the purpose and shall have experience in the testing of drugs, which in the opinion of the licensing authority is considered adequate. It is proposed that a degree in Veterinary Science should also be included in the qualification as referred above in this Rule 71 (4A) as this degree is no way inferior to any other degrees envisaged in the Rule. Further, it will be most appropriate to allow a person possessing degree in Veterinary Science to deal with testing laboratory responsible for the quality assurance of Veterinary Biologicals. Hence, a degree in Veterinary Science be included in the Rule 71 (4A).

After the discussion, the members unanimously agreed with the proposal to incorporate degree in Veterinary Science as a qualification under Rule 71[(4A)] of Drugs and Cosmetics Rules.

Item No.12: Create awareness among the consumers about the adverse consequences of self-medication of antibiotics.

Delhi Society for Promotion of Rational Use of Drugs (DSPRUD) organized a meeting involving expert group to try and see how sale of antibiotics over the counter could be prevented in the State of Delhi. The recommendations of this high powered meeting are as under:

1. Create awareness among the consumers about the adverse consequences of self-medication of antibiotics: It was felt that educating the consumers about the ill effects of self medication of antibiotics like – serious complications associated with self-medication and development of resistance in a simple consumer friendly language would be an effective measure to curb self-medication of antibiotics. The educated consumers will also serve as influencer's for their dear and near one's and associates.

   In the present family structure/system, the school children (10^{th} – 12^{th} standard) and elderly individuals (above the age of 50 years) have an influence over the family members and associates. To achieve this, the help of NGO's, resident welfare associations, Helpage, Rotary clubs should be taken to deliver the message by an expert to a large audience during their meetings.

   A simple consumer friendly message "Do not buy antibiotics without prescription" should be widely disseminated through the television and print media. Besides, the message can be given in the form of posters/leaflets in Hospital Pharmacies, Pharmacist's shop, private

clinics, Hospitals and schools and collages. Debate on the subject should also be held in schools and collages.

Educating the media: A media workshop should be held to educate the media people on the harmful effects of self medication of antibiotics to the society – lack of essential and life saving antibiotics available for treatment of several serious disorders due to development of resistance besides adverse complications to antibiotics. This will enable them to understand the magnitude of the situation and seek their involvement in creating news on the subject.

2. Create awareness among the chemists and druggists about the adverse consequences of self-medication of antibiotics: Chemists/Pharmacists have a very crucial role to play and their active participation was essential in preventing the sale of antibiotics without a prescription. Most of the chemists in our country are not qualified and educated to understand the implication of OTC sale of antibiotics. Therefore, it was felt that educating the Chemists and Druggists and creating awareness will effectively solve the problem of OTC sale of antibiotics.

   The education can be imparted by holding a talk by an expert in Chemists and Druggists association at a territory/state/National level. Informative articles by experts and key opinion leaders should be released in Chemists' association journals. These journals go to all the registered members of the association. The help of Pharmacy colleges in the country can be sought for giving special emphasis on the OTC sale of antibiotics and associated complications.

3. Strengthening the legislation: Private Pharmacies/Chemists shops should be manned by a qualified pharmacist. The legislation should be made more stringent and the regulatory infrastructure made more stronger to be able to make stricter checks and controls and punish the offenders. To this effect following specific recommendations were made:

   - Law should be made sufficiently stringent for the chemists to adhere to the law in terms of sale of antibiotics without prescription.
   - Enforcing sale of antibiotics strictly through issuing a bill (cash memo).
   - Additional powers may be provided in the Drugs and Cosmetics Act for cancellation of licence of the offending chemist.
   - Photograph of the chemist to be displayed on the shop to ensure the presence of a qualified pharmacist.

- **Sub-grouping of the Schedule H to include special provisions for antibiotics that is more stringent in terms of punishment.**

The Chairman informed the members that concern about improper use of antibiotics and its consequences has been raised at various fora. The Delhi Society for Promotion of Rational Use of Drugs (DSPRUD) organized a meeting regarding the strategy to be followed for indiscriminate use/sale of antibiotics over the counter and suggested to:

1. Create awareness among the consumers about the adverse consequences of self-medication of antibiotics.
2. Create awareness among the chemists and druggists about the adverse consequences of self-medication and inadequate administration of antibiotics.
3. Strengthening the legislation.

The Chairman requested the members to ensure a strict check on the sale of antibiotics across the counter. The chemist and druggist associations should be informed that no antibiotic preparations should be dispensed without the prescription of registered medical practitioner, as the antibiotics are already covered under Schedule H of Drugs and Cosmetics Rules. The chemist and druggist associations should be informed that cash/credit memo should be specially maintained as required under Rule 65 of Drugs and Cosmetics Rules. On this issue, Drug Controller Bihar informed that in the State of Bihar all the chemist and druggist associations have already been informed about the adverse consequences of self medication of antibiotics and the chemist and druggist associations have agreed to inform the consumers about the adverse effects of self medication of antibiotics.

As regards to strengthening the legislature, the Drugs Controller Delhi has suggested that a photograph of pharmacist (duly signed by the Licensing Authority) should be pasted on the Licence and Licence should be displayed on the prominent place of the establishment. Accordingly, the DCC unanimously agreed with the views of Drugs Controller, Delhi. It was also recommended that the IEC activity under Capacity Building Project should be utilized to address this issue. Also stricter vigil to be kept on antibiotics, which are more likely to be dispensed without prescriptions.

Item No.13 : Annual statistics in respect of manufacture, import and export of psychotropic substances and narcotic drugs from the states.

All the states may be aware that as India is a signatory to UN Convention 1971, the Directorate General of Health Services is required to furnish every year the information pertaining to 1)

Annual statistics regarding manufacture of psychotropic substances included in different schedules of 1971 Convention in Form P and 2) assessment of annual medical and scientific requirements for substances in schedule II, III & IV in Form B/P and 3) annual statistic of production, manufacture, consumption, stocks and seizures of narcotics drugs to narcotic control bureau, New Delhi for onwards transmission to INCB, Vienna. The INCB mission who visited India in May in their report desired the strengthening of mechanism for collection of data relating to manufacture consumptions balance in hand in respect of psychotropic substances and narcotic drugs. This Directorate has been visiting all the states every year to furnish the above said information directly to NCB, New Delhi. In spite of concerted efforts, the information was not fully coming from all the states. The secretary (Health) has, therefore, taken up the matter with defaulting states for expediting information. This matter was also taken up in 34th DCC meeting and all the states were requested to send the requisite information to NCB, New Delhi directly under intimation to this Directorate. Further, this Directorate requires a list of manufacturers of psychotropic substances with year wise statistical data on drugs manufactured by the firm for last 3 years and their complete address with Tel. No., Fax No., Email Address.

The Chairman reminded the members of DCC that the issue of providing annual statistics in respect of Narcotics Drugs and Psychotropic Substances Act has not been dissolved inspite of repeated discussions in the DCC meeting. In case there is any specific difficulty, the member should convey the same in writing so that the difficulties, if any, may be properly explained to the NCB.

Item No.14 : Insertion of Part I G in Schedule M relating to specific requirements of premises, equipments and materials for manufacture of non-sterilized and non-medicated surgical dressings

Manufacturing of bandages in the country is with the cottage level industry and the cloth used as raw material for manufacturing of such bandages are usually obtained from handloom sector.

Some purchasing organizations insist for WHO GMP Certificate for bandages and absorbent cotton. In fact, those organizations are not aware of complexity involving products like non-sterilized bandages and included as one of the essential criteria of producing WHO GMP Certificate in the bid. In view of this, a group consisting of Drugs Controllers of Delhi, UP, Rajasthan, Director CIPL and JDCI, CDSCO, North Zone was constituted to examine the issue in its totality and suggest the manufacturing norms which may be relevant to this sector of industry. The group recommended that there should

be minimum bench marks of GMP requirements in Schedule M to monitor control on raw materials etc. Since these items are also being purchased and used by the Govt. institutions, it is purposed that requirements should also be laid down of the purpose to have sanitation, hygienic conditions, storage, QC, documentation, distribution records etc.

In view of the above, it is proposed that a new Part I G in Schedule M relating to specific requirements of premises, equipments and materials for manufacture of non-sterilized and non-medicated surgical dressings may be incorporated.

DCC may kindly consider and give its recommendation.

The Chairman informed the committee that some purchase organizations were insisting for WHO GMP Certificate for surgical bandages and absorbent cotton to qualify for tenders. On the other hand, there is no specific WHO guidelines for surgical bandages and absorbent cotton. The matter was examined by a group consisting of members – Drug Controller Delhi, UP, Rajasthan, Director, CIPL, and JDC(I) North Zone. The group recommended the minimum benchmarks of GMP requirement in Schedule M to monitor control of raw materials etc. These requirements should also be read with the general requirements as mentioned in Schedule M on sanitation, hygienic conditions, storage, Quality control, documentation. distribution, records etc.

Based on the discussion held on the proposed draft vis a vis the requirement of schedule M the DCC agreed with the proposal to amend schedule M as per proposed draft of Part 1G.

Item No.15 : Grant of WHO GMP certificate as one of the eligibility criteria to quality to participate in institutional supply of drugs for domestic purposes

34th DCC in its meeting held on April 9, 2002, had deliberated (vide agenda no. 15) matters regarding grant of COP for surgical dressings. Since there are no specific norms prescribed under WHO GMPs guidelines, the members were informed not to entertain request from purchasing institutions for issuing such certificates to the manufacturers of surgical dressings like rolled bandages/gauges etc. In view of this, the members were also requested to advise all purchasing organizations/departments in their state to refrain from insisting on such certificates for the said items.

Representations were received on difficulties being faced by them to obtain such certificates for various dosage forms and are thus unable

to participate in the institutional supplies for domestic purposes. Furthermore, it seems that there is no uniformity in the grant of such certificates relating to different dosage forms.

DCC may deliberate and give its recommendation.

The Chairman informed that many State Drugs Controllers are issuing WHO GMP certificates to the manufacturers in order to participate in institutional supply of drugs for domestic purposes. On the other hand, there is no specific guidelines prescribed for issuing of WHO GMP certificates for this purpose. These views are also endorsed by the WHO SEARO office, New Delhi. Also, there is an issue of different standards. The procurement organizations are of course free to lay down their own specific requirements for a supplier.

To have uniform approach, all State licensing Authorities have been informed not to consider WHO GMP certificates to the manufacturers for participation in the institutional supply. The matter has also been dragged in courts and stays have been granted. Further this Directorate by constituting expert group also framed guidelines in respect of specific requirement for manufacturer of non-sterilized and non-medicated surgical dressings. Accordingly, the DCC noted the viewpoints and unanimously agreed regarding non-issuance of WHO GMP certificates in respect of surgical dressings and absorbent cotton etc. and limit it to international commerce. Members may, however, examine the alternate mechanism of GMP certification as provided in TRS.

Item No.16 : Non-availability of long acting penicillin injection

Of late, there are reports about an acute non-supply of long acting penicillin injections. This is a life saving medicine and is required to be taken by all the patients with rheumatic fever or rheumatic heart disease.

The prevalence of rheumatic heart disease in India is 6 per 1000 and the disease involves the younger generation. Over 40-50 lakh children and young adults require this injection on a monthly basis. If not taken, rheumatic fever can get reactivated and can lead to further damage to the cardiac valves. DCC may discuss the modalities in identifying drug shortage and the remedial measures.

The Chairman informed that non-supply of long acting penicillin injection has been reported from various corners. The long acting penicillin injection is the drug of choice for treatment of Rheumatic Heart Disease (RHD). The prevalence of RHD is 0.6% and about 40-50 lakh children

and young adults require this injection on monthly basis. If the drug is not available the disease can further damage cardiac valves.

Based on the reported shortage, the Chairman requested the members to ensure the availability of long acting penicillin injection. Accordingly, the members agreed with the suggestions of the chairman. The Chairman also requested the members to furnish details about the name of manufacturer and its production details to this Directorate as and when such shortages are noticed.

Item No.17 : **Compliance regarding recycle of used disposable needles and syringes in health care system**

The issue of recycled use of disposable needles and syringes in health care system was deliberated in 33rd DCC (Agenda items no. 2) and 34th DCC (Agenda item no. 2 of 33rd DCC) wherein the general apprehensions in public mind about widespread reuse of this item still continues. Recently, serious concern has also been expressed by the Parliament that disposable needles and syringes found in dumps on the backyard of hospitals and collected as infected pieces of plastic, sold them to kabariwalas, passed to unscrupulous repackers and soon these disposable syringes find their way to nursing homes. Although the members, in general have informed that no instances have been reported regarding recycling of used disposable needles and syringes in the health care system in their State, it seems that the problem continues to persist.

In this connection, members of DCC may exercise great care to see that the alleged sale of recycled used disposable needles and syringes is dealt with heavy hand. They should keep a strict watch over the retail outlets, which are licensed by them opposite to hospitals, nursing homes etc. They should ask their field officers to keep strict vigil over this activity in their areas. They may also consider taking action against such persons indulging in this unhealthy activity.

The Chairman informed that from time to time, instances have been reported in the media regarding the alleged recycle of disposable needles and syringes in the health care delivery system. A general apprehension in public mind about widespread reuse of these items still persists. Nonetheless serious concern has also been expressed by the parliament that disposable syringes and needles are found dumped on the backyard of hospital and collected as infected piece of plastic, sold to Kabariwalas, passed to unscrupulous repackers and soon these disposable syringes may find their way to nursing homes.

The Chairman requested the members to keep a strict vigil over any such possible unscrupulous activity and also take punitive action against persons involved in such unethical practice. While on discussion, Drug Controller Haryana informed the committee that one case has been reported in the State about the reuse of syringes without sterilization and the prosecution has been launched. Other members informed that no such incident has been reported in their states. The DCC, however, agreed with the view point of the chairman to keep a strict vigil over any reuse of disposable syringes and needles and that action taken report in this regard would be furnished to this Directorate on quarterly basis.

Item No.18 : Testing of HIV, HBsAg and HCV test kits

During the Technical Committee meeting held by NACO, it has been decided to check the quality of HIV, HBsAg and HCV test kits moving in the market. In this regard, NACO agreed to provide financial assistance to the States for drawing the samples as well as forwarding the same in cold chain package to NIB, NOIDA. The representative of NIB NOIDA suggested that 100 to 200 tests of the above kits are required for evaluation. The cost of the kits as well as the charges of sending the samples to cold chain will be borne by NACO. The samples of the above test kits may be drawn from the manufacturers' premises or from the distributor or from blood banks.

The members of the DCC may deliberate this issue and give their opinion.

During the discussion the Chairman informed that NIB Noida conducts testing of HIV, HbsAg and HCV test kits in respect of sensitivity and specificity. Based on the satisfactory evaluation of test kits, the same is declared to be of standard quality. To answer the specific query raised by Drug Controller Karnataka in respect of test of samples of diagnostic kits by NIB Noida, the Chairman informed that NIB is the only statutory lab to undertake the testing of such diagnostic kits. The sample drawn from the manufacturing premise, distributors or from blood banks can be sent to the NIB under cold chain condition and NACO has agreed to provide financial assistance to the States for drawing samples as well as forwarding the same in cold chain package to NIB Noida. Accordingly the committee noted the modality for sending the samples of diagnostic kits to NIB Noida.

Item No.19 : Proposal to incorporate one more type of standard for surgical gauze & bandage cloth in Schedule F(II) of the Drugs and Cosmetics Rules, 1945

The Surgical Dressing Manufacturer's Association, Chattrapatti, Tamil Nadu has made a representation to amend Schedule F(II) of Drugs and Cosmetics Rules in respect of Standard for Surgical Dressing viz. absorbent gauze & bandage cloth. In this connection, a sub-committee was constituted by 33rd DCC under the chairmanship of Drugs Controller, Tamil Nadu to examine the issue. The subcommittee meeting was held on 30th & 31st January, 2004 at CDTL, Chennai. The committee examined the representation forwarded by the association and finally decided to incorporate one more type of surgical gauze & bandage cloth in Schedule F(II) with the following standards. The existing standards for absorbent gauze & bandage cloth will be called as Type A & the proposed incorporation to another type will be called as Type B.

The Chairman informed that in the last meeting, a sub-committee was constituted to amend Schedule F – II of Drugs and Cosmetics Rules in respect of standards of surgical dressings namely absorbent gauze and bandage cloth. The issue to amend Schedule F-II was raised by the surgical dressings manufacturers association, Tamilnadu. The committee have now submitted their report and proposed certain amendments in Schedule F-II and also to incorporate one more type of standards for surgical gauze and bandage cloth. The Chairman requested FDA Maharashtra to explain the overall recommendations of the sub-committee of which he was the Chairman. It was explained by Mr. Khobragade that the sub-committee has taken care of all points raised by the manufacturers and proposed to incorporate one more type of standard for surgical gauze and bandage cloth as secondary choice to the buyers. Based on the discussion held on the sub-committee report, the DCC agreed for incorporation of revised standards. However, the chairman requested the members to still examine and give their comments within one month's time failing which it would be presumed that members are in agreement with the recommendations of the sub-committee.

Item No.20 : Off label use of drugs

Recently, cases have been reported about use of drugs for an indication, which has not been formally approved by the regulatory authority. While examining the reported incidents, it has been observed that use of a drug by a clinician for unapproved indication is considered as off label use of a particular drug. It has been further verified that regulatory agencies like US FDA do not recognize the prevalence of off label use of drugs.

It would be seen that off label use of drugs by medical practitioners may be out of scope of direct intervention by drug regulatory authorities in the context of available provisions under Drugs and

Cosmetics Act & Rules. A committee of experts which had examined various issues concerning off label use of drugs have suggested that relevant provision in respect of off label use of drugs under certain conditions by medical practitioners for an indication not formally approved may be incorporated in Drugs and Cosmetics Rules.

DCC may examine the issue.

Chairman explained in detail the issues concerning off label use of drugs, which has recently come in limelight. Cases have been reported about use of drugs for an indication, which has not been formally approved by the regulatory authority. In India there is no mechanism to clearly define the concept of off label use of drugs, which has led to the confusion among the medical fraternity and regulatory authority. The issue emerged from Letrozole controversy involving its use by the gynaecologists for treatment of infertility. The Chairman also informed the members that US FDA, TGA, MCA etc. do recognize the off label use of Drug as a prerogative of medical practitioner. However, a committee constituted under Additional DG to examine the alleged unauthorized use of letrozole felt that the Drugs and Cosmetics Act be amended to check off label use of drugs by medical practitioners. The issue was deliberated extensively. It was noted that off label use of drugs in some form or other covers number of drugs. Even, some new indications of drugs have been regularized only after reports about their such usefulness. The committee was of the view that amending the Act or Rules would not be feasible.

It was, however, agreed to get this issue further examined through the legal sub-committee to be constituted by DCC.

D. State Agenda Items

Assam

Item No.21 : Not to be disposed off order in form 15 under Drugs and Cosmetics Act

The period of 20 days of not to disposed off order should be enhanced beyond 20 days (section 22 (c) (iii) because it takes time for procedural follow up action etc.

After the discussion it emerged that enhancement of time limit to more than 20 days for not to dispose off order in Form 15, under the Drugs and Cosmetics Act involves amendment under Section 22 (c) iii. Accordingly

its was decided that the matter may be examined by the Legal Sub Committee.

Item No.22 : **The summary trial under Section 36 (A)**

This practically does not work hence the power should be envisaged to Inspector of drugs and should be more practical.

After the discussion the committee agreed with the proposal to amend Section 36 (A) of Drugs and Cosmetics Act. The issue involves amendment under Section 36 (A) and therefore it was decided to get the proposal examined through the legal sub committee for suggesting appropriate changes etc.

Item No.23 : **The provision for restricted licence to premises in Form 20 A/ 21 A**

These provisions should be abolished because qualified pharmacists are coming up and rural areas are electrified.

The issue involves services of qualified pharmacists as against the prescribed non-qualified persons and access to drugs. The proposal, therefore, needs to be examined by the subcommittee on enforcement issues.

Item No.24 : **Specific definitions**

The definitions under Drugs and Cosmetics Act for "Counterfeit" and "Similar drugs" should be specified.

The Chairman informed the committee that this issue was deliberated by the committee headed by DGHS constituted by Ministry to examine the issues concerning spurious drugs. The committee had strongly recommended that State Drugs Controllers should not allow licensing of products with similar sounding names or look alike brand names.

Andhra Pradesh

Item No.25 : **Date expired pharmaceutical products**

Following points are mentioned to bring the notice of the DCC members:

1. **Expiry drugs should not be returned to manufacturers. Some manufacturers may make reprocess the drugs. It may be possible with manufacturers. So the expiry drugs shall be**

ordered to destroy in the end points, not in the manufacturing point.

2. Expiry drugs should be destroyed in the presence of the competent authorities not below the rank of Drugs Inspectors or Authorized Officers at any time after the date of expiry. Then a certificate may be issued by the authority. That certificate is useful for recovery/replacement/payment.
3. Expiry drugs, should not reach the public/people to use at any cost.
4. For expiry drugs, the manufacturer/wholesalers should give credit note/replacement/payment/for actual rate.
5. Expiry drugs should not be kept in the hand of people/public/medical stores and should not be thrown out to the street. It should be destroyed.

DCC to consider for necessary amendment of provision of Drugs and Cosmetics Act 1940 with a new set of legislations and suitable enforcement for returned drugs, date expiry drugs.

Please refer to the Minutes of Item No. 9. It was agreed by the committee that the enforcement subcommittee would provide specific modalities/guidelines to be followed by all State authorities in respect of expiry of drugs.

Goa

Item No.26 : Consideration of need to provide provisions under the Drugs and Cosmetics Rules requiring Medical Practitioners/Hospitals/Nursing Homes to report adverse drug reactions to State Drug Controllers

Many a times, it is noted that certain adverse drug reactions occur due to use of certain drug formulations to the patients and such matters are not reported by Medical Practitioners/Hospitals/Nursing Homes, to any authority and hence, it goes unnoticed. In view of this, it is suggested that certain provisions should be made under the Drugs and Cosmetics Rules, so that if any adverse drug reaction occurs or grievous hurt or death is caused due to administration of any drug to a patient, the same should be reported to the State Drug Controller, and in turn, State Drug Controller should report to the Drugs Controller General (India), so that the data with respect to that drug can be compiled about adverse drug reaction at national level. For the said purpose, it is also suggested that a format should be designed for reporting adverse drug reaction/grievous, hurt/death by the Medical Practitioners/Hospitals/Nursing Homes etc., to the State Drug

Controller. Members should deliberate on the matter. If agreed, a suitable amendment may be made on the following lines:

"The medical practitioners carrying on their profession in any State shall report all occurrences of adverse drug reaction/grievous, hurt/death caused due to administration of any formulation to the patient, to the State Drug Controller in the prescribed format."

Drug Controller Goa informed the members that there is a need to amend Drugs and Cosmetics Rules in such a way that Registered Medical practitioners attached with hospitals/Nursing Homes should report any Adverse Drug Reaction (ADR) to State Drugs Controllers and State Drugs Controllers would in turn report to the DCG (I) so that the data with respect to drug related adverse reactions would help to monitor the safety and efficacy of drugs.

The chairman informed the members that the issue is not so simple as it appears to be. No country has such legislation. Moreover in India, the modalities adopted by medical practitioners is much different than those of developed countries. However, a National Pharmacovigilence Programme is soon going to start with Zonal, Regional and Peripheral centers across the country to monitor spontaneous adverse drug reactions. Therefore, there is no need to amend the Rules. The chairman further added that ADR reporting couldn't be done by imposing law on the medical practitioners, as it is a voluntary activity. Need of the hour is to sensitize medical practitioners for reporting ADRs. However, members informed the Chairman that they are not aware of any such activity being conducted at the national level. The Chairman clarified that a copy of proposed National Pharmacovigilence Programme with its organizational structure will be circulated separately to all state drug controllers for information as soon as the programme is given final clearance by the Govt.

Item No.27 : Consideration of the question to delete the product from the list of Schedule category, once said product is included in Schedule K of the Drugs & Cosmetics Rules

This Directorate has permitted to manufacture fixed dose combination of levonorgestrel & ethinyl estradiol tablets U.S.P. as chemical contraceptive in different strengths and now the same has been included under Schedule K of the Drugs and Cosmetics Rules, vide Notification No. GSR 648(E) dated 16/9/2002. Since the said formulation in included in Schedule II list, therefore, they are also printing 'Schedule H Warning'. It is felt that since the sale of the product is exempted under Schedule K, therefore, warning specified for Schedule H drugs is redundant. In view of the above, it is requested that the same should be either be excluded from the list of

Schedule H drugs or directives to be issued to delete Schedule H Warning.

The Drugs Controller Goa informed that many products like fixed dose combination of levonorgestrel and ethinyl estradiol USP tablets have been listed under Schedule K of Drugs and Cosmetics Rules. On the contrary, the same product has also been listed in Schedule H. it is therefore suggested to delete such products from Schedule H.

Based on the discussion held, the committee agreed unanimously that office of DCG (I) may examine the products listed in Schedule K vis a vis Schedule H and take required action in the matter.

Item No.28 : **Consideration of the question for stating the dosage form for which the clearance has been granted by the Drugs Controller General (India) as new drug**

The Drugs Controller General (India) sends periodically all State Licensing Authorities, the list of "New Drugs" cleared by him. However, the type of formulations cleared by Drugs Controller General (India) is not mentioned in the list, with the result the State Licensing Authorities totally remain in dark, and as and when the parties approach the Licensing Authority, after completion of 4 years, it becomes very difficult to know that which dosage form was cleared by the Drugs Controller General (India). N view of the above, it is requested that as and when the product is cleared by the Drugs Controller General (India), the dosage form should also be mentioned on the list of products, so that there is clear cut transparency in the matter.

The Chairman agreed to incorporate the type of dosage form etc. at the time of issuing list of products as new drugs and informed to the members that the same would also be displayed on the website www.cdsco.nic.in.

Item No.29 : **Consideration of the question of amending the language contents of Section 18 of the Drugs and Cosmetics Act, 1940**

Section 18, interalia, states that "No person shall himself or by any other person on his behalf" (c) manufacture for sale or for distribution, or sell, or stock or exhibition or offer for sale, or distribute any drug or cosmetics, except in accordance with the condition of a licence issued for such purposes under this Chapter.

It is observed that under the Drugs and Cosmetics Act, stocking of a drug without a licence is an offence. There have been in the past several Apex Court judgements ruling that mere stocking or

possession of a drug meant for sale, is an offence and the ingredient to prove the component of a sale was never a precondition.

However, recently, the High Court of Mumbai at Goa Bench, has in the matter filed by this Directorate, where large quantities of drugs were found stocked in a nursing home, which was run by unqualified persons and was prosecuted by this Directorate for possession/stocking of drugs without licence. The lower Courts convicted the accused, but the High Court of Mumbai at Goa Bench, in their judgement, ruled that unless the component of the sale has been established, no offence could be made out merely by stocking of drugs.

In light of the above judgement, several other cases have been severely affected. Hence, it is proposed that after the word "stock" in Section 18 (C), a coma should be introduced to make stocking independent from the sale component.

The Drug Controller Goa informed that recently a judgment has been passed by the Honourable High Court of Bombay at Goa Bench ruling that unless the component of sale has been established, no offence could be made out of merely by stocking of drugs. In the light of this judgment several other cases have also been severely affected. It is, therefore, proposed that after the world "stock" in Section 18(C), a coma should be introduced to make stocking independent from the sale component.

After the discussion the Chairman agreed with the proposal to amend the language content of Section 18 (C) of Drugs and Cosmetics Act 1940 and to forward the proposal to the Ministry for taking necessary action.

Item No.30 : Consideration of the question as to whether Cephalosporin group of products should be manufactured under Beta-lactam Section or under General Section

It has come to notice of this Directorate that some of the States are permitting Cephalosporin group of products under Beta-lactam Section, while some States are permitting the said products under General Section, as per the decision taken in the 24th DCC, under Item No. 3(b) held in New Delhi on 8th & 9th January, 1985. In order to have uniformity all over the country, suitable guidelines may please be issued in this regard.

The Drug Controller Goa informed that some of the states are permitting Cephalosporin group of products under Beta-lactam Section, while some states are permitting the said products under General Section, as per the decision take in the 24th DCC under item No. 3(b). On this issue Drug

Controller Delhi informed that US FDA guidelines speak about the manufacturing requirements for penicillin group of antibiotics beta lactam. He further added that cephalosporins are group of antibiotics closely related to the penicillins.

After the discussion it was decided that the proposal would be examined by DDC(I) (WZ) in consultation with FDA Maharashtra so as to make fresh guidelines regarding manufacture of beta lactam group of antibiotics. These guidelines would supercede the previous decision taken in the 24th DCC Meeting.

Kerala

Item No.31 : Amendment proposed in Schedule 'K' of the Drugs and Cosmetics Rules 1945

Schedule 'K' of the Drugs and Cosmetics Rules, 1945 provides for exemption to Registered Medical Practitioners who supply drugs to their own patients from taking out licence. The practitioners are bound to purchase drugs from licensed dealers or manufacturers and to keep records of supplies with details. But many practitioners supply date expired drugs to patients and do not observe conditions of storage. It is necessary to control and monitor the supplies of drugs by Medical Practitioners. The provisions of Schedule 'K' should be amended to make applicable to the conditions of licence under Rule 65(17).

The Drug Controller Kerala proposed that the provisions of Schedule K should be amended so as to make the conditions of licence under Rule 65 (17) applicable in respect of registered medical practitioners who supply drugs to their own patients. While making deliberations on the proposal the chairman informed that the proposal has already been taken up in the last DCC wherein it was decided that the opinion of Indian Medical Association should be obtained before amending the provisions of Schedule K and also the category of drugs which are to be stopped. The matter is being pursued with IMA. However, the subcommittee of DCC on enforcement issue may examine this. Supply of drugs to medical practitioners is quite considerable

Item No.32 : Rule 66 of the Drugs and Cosmetics Rules

It gives powers to suspend or cancel the licences for contravention of the provisions of the Act and Rules. It is necessary to give compounding powers to the licensing authorities for violation of the conditions of licences.

(3) A conspicuous red vertical line in the left side running throughout the body of the label, which shall not be less than one mm in width and without disturbing the conditions printed on the label to depict that it is a prescription drug.

(4) Proper name of the drug shall be printed or written in indeble ink and shall appear in a more conspicuous manner than the trade name, if any, shall be shown immediately after or under the proper name on the label on the innermost container of the drug or every other covering in which the container is packed.

2 In Part X-A of Drugs and Cosmetics Rules (as inserted vide G.S.R. No. 944 (Edt. 21.9.1988), there are Rule 122-B (Application for approval to manufacture new drug other than drugs classified under Schedule C and C1) and 122-C (Application for approval to manufacture new drug classified under Schedule C and C1).

In Part X-A of Drugs and Cosmetics Rules, the recent amendment vide G.S.R. No. 900 (E) dt. 12.12.2001, the Rule 122-C is omitted and Rule 122-B in Clause No. (1) is amended as follows:

"Rule 122-B Clause (1)(a) says No New Drug shall be manufactured for sale unless it is approved by the licensing authority defined in Clause (b) of Rule 21."

In the amendment as notified in G.S.R. No. 900 (E) dt. 12.12.2001, the Rule 122-C has been omitted which has relates to drug under C and C1 but Rule 122-B reads as "Application for approval for manufacture new drug other than drug classified under Schedule C and C1" which is contradictory. Therefore, Rule 122-B may be amended as "Application for approval to manufacture a New Drug".

The Chairman informed to the members that at the time of granting approval under Form 122-A or 122-B, the product specifications in respect of name, content of active ingredients, dosage form, indications, etc. is mentioned. While approving, a copy of the package insert, specimen label is required to be submitted as per the provisions in Form 44. Therefore, it is not required to add a new schedule. The committee was informed that all drugs approved along with its dosage form shall be displayed on the website. Rule 122-B is being amended to correct the heading under Rule 122-B. The members of DCC, however did not agree to the proposal for adding a new Schedule to the Rules for listing of new drugs.

Item No.42 : Not to be disposed off order in Form 15 under Drugs and Cosmetics Act

As completion of an investigation normally takes more than twenty days and further renewal of the order for not disposing stocks in Form 15 is not as per the spirit of the law, the Drugs Inspector may issue such orders for a period not exceeding 90 days from issue of the order. The Rule 54 of the Drugs and Cosmetics Rules, 1945 needs to be amended suitably to enable the Drugs Inspectors to issue orders in Form 15 for a period not exceeding 90 days.

Drugs Controller Orissa informed that completion of an investigation normally takes more than 20 days and further renewal of the order for not disposing stocks in Form 15 is not as per the spirit of the law. The Drugs Inspector may issue such orders for a period not exceeding 90 days from the issue of order. Therefore Rule 54 of the Drugs and Cosmetics Rules needs to be amended suitably to enable the Drugs Inspectors to issue the order in Form 15 for a period not exceeding 90 days.

After the discussion it was decided to refer the matter to legal subcommittee of DCC.

Item No.43 : Suggested amendments in Schedule K

Sl. No. 12. Substances intended to be Used for destruction of vermin or insects which causes disease in human beings or animals viz. insecticides and disinfectants.	**The provision of Chapter IV of the Act and Rules thereunder which require them to be covered by a sale licence subject to the condition that** **(1) Provision of condition (17) of Rules 65 of the Drugs and Cosmetics Rules, 1945.**

Omission: The word "insecticides" needs to be omitted since this has been omitted from Rule 128 vide G.S.R. No. 139 dt. 8.1.1976.

U/R. 123 in Schedule K, Sl. No. 12 the word "insecticides" may be deleted in view of the amendment vide G.S.R. No. 139 dt. 8.1.1976.

The DCC agreed with the proposal to amend Schedule K in respect of Serial No. 12 and that word "insecticide" may be deleted in view of the amendment vide GSR No. 139 dated 8.1.1976.

Item No.44 : Inclusion of canula in Schedule R1

The standards for sterile disposable perfusion set, sterile hypodermic syringe and needles have been prescribed under Schedule R(1), but the 'Canula', which is also a hypodermic device conforming the definition drug under Section 3(b)(iv) of Drugs and Cosmetics Act,

The Drug Controller Kerala proposed to amend Rule 66 of Drugs and Cosmetics Rules so as to provide compounding powers to the licensing authorities for violation of the conditions of the licence.

On this proposal the Chairman informed that the provision related to compounding of offences is one of the recommendations of the Mashelkar Committee's Report and same is being considered by the Ministry.

Item No.33 : Computer sales bills

The majority of the retail dealers are now maintaining computer sales bills, the system of keeping registers under Rules 65(3)(i) and 65(4)(i) is not practically in existence. As the dealers are free to exercise their options to maintain carbon copies of bills, the provisions regarding maintenance of registers may be deleted.

The Chairman informed that the issue regarding maintenance of computer sales bills and the system of keeping registers under Rule 65(3)(i) and 65(4)(i) has already been discussed in the last DCC and it was decided that the hard copies of the computer bills is also to be maintained, inter alia the other requirements. The members further informed to the Chairman that the supply by retail sales shall be recorded at the time of supply either in a register or in a cash/credit memo book. Therefore the committee felt that there is no need to delete "register" under rules 65(4)(i) of the Drugs and Cosmetics Rules.

Item No.34 : Qualification of Inspectors and Controlling authority

The qualification prescribed by Rules 49 and 50-A is degree in Pharmacy or Pharmaceutical Chemistry or in Medicine with specialization in Clinical Pharmacology or Microbiology. The Qualification degree in Medicine has no relevance now a days as large number of adequately qualified pharmacy graduates are available. The qualification degree in medicine may be deleted from Rules 49 and 50-A.

The issue regarding deletion of qualification of degree in medicine under Rule 49 and 50-A was discussed in the context of availability of large number of adequately qualified pharmacy graduates in the country. During discussion the members expressed different opinions. The committee also observed that merely having a qualification in the medicine would not qualify the requirements of a licensing authority unless a person should also have an experience in manufacturing or testing of drugs or enforcement of the provisions of the Act. Many members suggested that under the existing provisions, there is a wider choice in the recruitment.

After discussion it was felt that time has not ripened to delete the qualification of medicine under Rule 49 and 50-A. However, the enforcement subcommittee of DCC should further examine this issue.

Item No.35 : Licensing of Private Hospitals

The issue of licensing of private hospitals is now pending in the Supreme Court. It is necessary to exercise more vigil over the supplies of drugs made by private hospitals. Private hospitals are very likely to obtain drugs from unauthorized sources. Therefore, the provisions in Schedule 'K' requiring private hospitals to take out licenses for stocking and distributing drugs may be strengthened.

Drugs Controller Kerala informed that there is a need to exercise more vigil over the supplies of drugs made by private hospitals, as private hospitals are very likely to obtain drugs from unauthorized sources. Therefore, the provisions of Schedule K requiring private hospitals to take out licenses for stocking and distributing drugs may be strengthened. Some members informed the committee that this issue is already before the Hon'ble Supreme Court of India and the judgment is awaited. Accordingly it was decided that the proposal should be resolved after the judgment is passed by Hon'ble Supreme Court of India. It was, however, noted that even Mashelkar Committee has noted the need to also monitor drugs distributed through the channel of private practitioners and hospitals.

Item No.36 : Suggestion for amendment of the Drugs and Cosmetics Act, 1940 in respect of Section 22–(A)

There is wide spread confusion about Section 22-2(A) of the Act which was inserted with effect from 1/2/1983. the Section requires the Inspectors to return the seized documents to the persons from whom they were seized within twenty days. The inspectors are bound to produce the documents in the Courts after seizure and the Courts order safe custody of the records so produced. This is vital process in all criminal procedures. As such the requirements of returning the documents to the persons concerned will not be in the interest of justice. The documents produced before an Inspector can be returned as per Section 22-2 (A). But the documents seized should be kept under custody as per the order of the court.

During discussion it emerged that impounding of documents during the trials process is required under the Section 22-2(a) and there appears to be some procedural difficulty in returning the seized documents to the person from whom they were seized within 20 days. It was therefore agreed to

seek the specific opinion by taking it up with the Legal subcommittee of DCC.

Item No.37 : Qualification and experience of Ayurveda Drugs Inspectors

Rule 167 of the Rules prescribe diploma in Ayurveda, Siddha or Unani system as one of the qualification for Ayurveda Drugs Inspectors. The qualification is not relevant now and is not an adequate qualification for an inspector and may be deleted from Rule 167. It is also necessary to prescribe the duration of practical training required for graduates in pharmacy and degree holders in Ayurveda or Siddha or Unani Systems of Medicines.

As the proposal attracts the provisions relating to Indian system of medicine under Rule 167, it was decided that the proposal may be referred to the Department of ISM&H (AYUSH) for consideration.

Item No.38 : Consultation with expert in Ayurveda

The Govt. of India has amended the Drugs and Cosmetics Rules by adding Rule 162-A prescribing qualification of licensing Authority for Ayurveda, Siddha, or Unani drugs. In the circumstances consultation with an expert can be dispensed withy as the licensing Authorities are professionally qualified. Therefore, sub-rule (2) to Rule 154 may be deleted. This is necessary to avoid legal complications.

As the proposal concerns the provisions relating to Indian system of medicine under Rule 167, it was decided that the proposal may be referred to the Department of ISM&H (AYUSH) for appropriate consideration.

Item No.39 : Sales Licenses for Ayurveda drugs and raw materials

Good Manufacturing Practice for Ayurveda drugs places more importance on quality control of raw materials and finished goods. The situation that existed at the time of implementation of chapter IV A has changed to a large extent. As it is necessary to regulate the storage and sales of Ayurvedic drugs, suitable licensing systems may be introduced.

As the proposal attracts to the provisions relating to Indian system of medicine under Rule 167, it was decided that the proposal may be referred to the Department of ISM&H (AYUSH) for its consideration.

Item No.40 : Manufacture of Ayurvedic drugs by Vaidyas

As per Section 33EEC Vaidyas and Hakkims who manufacture medicines for the treatment of their own patients are exempted from taking out licence. This provision needs to be reconsidered. Vaidyas and Hakkims should be defined to include only Registered Medical Practitioners in the respective systems of medicine. The extent of exemption that can be given and the conditions of exemptions are also to be framed to prevent unauthorized manufacture of drugs.

As the proposal attracts to the provisions relating to Indian system of medicine under Rule 167, it was decided that the proposal may be referred to the Department of ISM&H (AYUSH) for its consideration.

Orissa

Item No.41 : New Drug approval – formation of new Schedule

1 The permission of a new drug formulation under Rule 122B, 122D are granted by the DCG(I) as the licensing authority under Rule 21 of Drugs and Cosmetics Rules. The DCG(I), after careful study of all required parameters, issue permission to the manufacturers in Form 46 of Drugs and Cosmetics Rules. On production of the same before State Licensing Authority, manufacturing licences are being granted to them. Since no existing schedule is applicable for such categories of new drugs, the labelling provisions as required under Rule 96 and 97 are also not applicable. Under these circumstances, a manufacturer may label the new drugs at their sweet will, which may at times be misleading but the regulatory authority has no legal provision to take any action against the erring firms under the existing provisions of Drugs and Cosmetics Act and Rules. Therefore, it is suggested that:

A) Where permission/approval for manufacturing of a new drug has been accorded in Form 46 (read with Rule 122-B and 122-D) of Drugs and Cosmetics Rules by Licensing Authority defined under Rule 21, the new drugs/fixed dose combinations of two or more drugs as defined under Rule 122-E may be incorporated in a new Schedule.

B) The new drugs/fixed dose combinations may clearly bear following labelling provisions on the innermost container of the drug or every other coverings in which the container is packed.

(1) "Schedule____ Drug Warning: To be sold by retail on the prescription of a _____only.
(2) If the formulation/drug contains a new drug included in the new Schedule be labelled with the symbol – Rx.

1940, which requires to be notified as a drug in the official gazette and included under the said schedule.

The Chairman informed the members that a sub committee on medical devices is to be constituted to examine the list of devices, which are to be notified as drugs. The report of the sub committee would be made available to the members for comments in due course of time.

Rajasthan

Item No.45 : Status of physician samples

Rule 65 (18) to Drugs and Cosmetics Rules vis-à-vis Rule 96(1)(IX) prescribe the status of physician sample. Over the period, it has been felt that the free distribution of these among prescribers does not serve any useful purpose but on the contrary there is a rampant misuse by way of clandestine consumption and at times, sale of such drugs by unscrupulous traders. Possibility of evading of revenue even cannot be ruled out. Thus, it is felt such a provision be omitted except free distribution of physician samples of "New Drugs".

While explaining the proposal the Drugs Controller Rajasthan brought to the notice of the committee that there has been news items about rampant misuse of physician samples by some unscrupulous traders. It is therefore felt that provision relating to distribution of free samples may be deleted except for free distribution of physician samples of new drugs only.

On the views expressed by Drugs controller Rajasthan, the Chairman took the opinion of members. The Drugs controller Delhi informed that a large number of physician samples are suspected being commercialized and a provision of distribution of physician samples to the medical professionals should be omitted from the Drugs and Cosmetics Rules. The Drugs Controller Andhra Pradesh felt the need for continuity of providing free distribution as it helps in ascertaining the quality/ safety aspects of the drugs by medical importance. Drugs Controller Karnataka suggested to the Chairman that instead of omitting we should regulate the provision as it plays an important role in the medical practice and the views of Indian Medical Association be obtained. The DDC(I) (WZ) informed that before omitting the rule the percentage of misuse is to be worked out. Our mandate is to regulate quality, safety and efficacy of drugs. Drugs Controller Goa opined that such samples are being misused and some times doctors charge as part of the treatment fees from the patients indirectly. The members apprised that some times the word "Physician Sample" is not incorporated on the label of the innermost container, which leads to its misuse.

Having obtained the views of the members, it was decided that proposal is to be got examined through subcommittee on enforcement issues. While examining the proposal, the subcommittee may also take views of the chemists and druggists associations, Indian Medical Association as well as manufacturers' associations.

Item No.46 : **Fixing norms for total quantum of drugs permitted to be stocked by Registered Medical Practitioners**

Various associations have brought to the notice that stock of drugs those stocked by such registered medical practitioners at times is more than even those stocked by some retailers and wholesalers. Hence, some restrictions require to be imposed upon in this direction.

On this issue, the Chairman informed that the issue has already been discussed in the last DCC and the matter is already been pursued with Indian Medical Association and further progress made in this matter would be informed to the members in due course of time. The issue also needs to be examined by subcommittee on enforcement matters.

Item No.47 : **Prescribing of application/licence forms for "Godowns"**

The wholesalers are generally the applicants for grant of licence for stocking of drugs in premises other than their principle set of premises. Under Schedule 'A' such forms at present does not exist. Hence necessary insertion in Rule 61, 63, 64 and Schedule 'A' be incorporated so as to streamline issue of licence for solely stocking of drugs by such traders.

Drugs Controller Rajasthan proposed that the whole-seller are generally stocking the drugs in premises other than their principal set of premises which is generally known as "godowns". Therefore a suitable type of Form, under Schedule A should be incorporated in order to regulate the stocking of drugs. On this proposal, the Chairman requested the members to share the practice adopted in their respective states. The Drugs Controller Delhi informed that godowns are used for extra storage of drugs and the addresses of such godowns can be mentioned on the main wholesale licence. There is no need for prescribing the separate licence for godowns. The Drugs controller Goa informed that if the applicant also desires to apply for a godown the same is also to be endorsed in their licence after physically verifying the premises.

Based on the discussion held on the proposal, the Chairman requested Drug Controller Rajasthan to suggest changes required to be incorporated in issuing the licenses to the godowns. However, in the meantime the

practice adopted by Drugs controller Goa may be followed. The issue would be examined by the subcommittee of DCC on legal matters.

Item No.48 : Services of registered pharmacists

1. **To ensure observance of good selling practice, the provisions of Rule 64 be amended to make mandatory to provide services of Registered Pharmacists for wholesale licence too.**
2. **Over the period, there has been mushroom growth of retail and wholesale establishments resulting into unfair competition and unfair trade practice. Hence, it would be worthwhile if it is made mandatory if issue of such licence is restricted to applicant where the registered pharmacist is either the proprietor or partner of such establishment and in case of wholesale establishment since registered pharmacist is better qualified, hence would serve better to monitor quality of drugs being traded.**
3. **Prescribing of fee in parallel to other provisions in respect of existing sale licences that any change in employment of an alternative registered pharmacist should also attract a definite fee for which necessary incorporation in Rule 61 be made which will strengthen the state revenue as well.**

While explaining the pivotal role of pharmacists in the healthcare delivery system the Drugs Controller Rajasthan proposed that we should engage the services of registered pharmacists for selling of drugs by way of wholesale also. To restrict the mushroom growth of retail outlets, such licence should only be issued to the applicants who hold diploma/degree in pharmacy and are owner or partner of the establishment. In the event of any change of pharmacist, the fee is to be collected from the applicant like it is done for change of licensee etc.

During the discussion, many were of the view that there is no need to amend the rules in respect of engaging the services of qualified pharmacist for distribution of drugs by way of whole sale licence as the patients are not directly in contact with the pharmacist. Accordingly, the DCC decided that there is at present no need to amend the Rule in respect of providing services of registered pharmacist for wholesale licence.

During discussion it emerged that the restriction of sale licence to registered pharmacists as one of the means to check mushroom growth of retailers would also have to be viewed in the context of fundamental rights. A subcommittee under the Chairmanship of Commissioner FDA, Gujarat, is already examining this issue. However, the committee has not come to any decision. The Commissioner FDA, Gujarat is to be requested

to examine the issue afresh and convey its opinion. While examining the issue, the views of trade associations may also be obtained.

During the discussion the members differed in opinion for levying fees on change of name of pharmacist to be endorsed in the same licence. It was decided that there is no need for levying a separate fees for changing the name of pharmacist as the license fees covers all aspects for regulating the provisions in the conditions of licence.

Item No.49 : **Guidelines for loan licence/contract manufacturing**

The existing provisions are not very explicit in respect of loan licence such as whether any fixed premises should be a prerequisite. At present, the loan licence are granted to applicants once they possess wholesale licence on Form 20-B and 21-B. There is a rampant growth of contract manufacturing which requires to be curbed forthwith as under existing provisions, it becomes difficult to fix the onus particularly in events where samples are declared as not of standard quality.

Drugs Controller Rajasthan explained that due to growth of contract manufacturing, it has become imperative to fix the onus particularly in the events where samples are declared as not of standard quality. On this issue the Drugs Controller Andhra Pradesh also suggested that only one brand name should be allowed to one manufacturer. Many members also informed that the contract manufacturing has now become a practice parallel to the system of loan licensing. Representative of Gujrat, however, emphasized that as far as general norms of quality is concerned, there does not appear to be any difficulty.

During discussion it was felt that the loan licence is recognized within the ambit of Drugs and Cosmetics Rules and the manufacturer has the prime responsibility for maintaining the quality, safety and efficacy of drugs. In the event of producing fraudulent medicine, the manufacturer is liable to be prosecuted. Contract manufacturing is practiced in developed nations as well. The system of loan license has been discussed by DCC many a times. There appears to be a need to re-examine the issue by the enforcement subcommittee.

Item No.50 : **Responsibility of approved testing laboratories on drugs declared as not of standard quality**

Some responsibility requires to be fixed where the manufacturer utilizes the services of private approved testing labs and in contrary to their test report the statutory samples when are declared as not of standard quality by Govt. Analyst.

After discussion, it was decided that the issue needs to be discussed in Government Analyst Conference. For this purpose Chairman requested Director, CDL, Kolkata to revive the committee. It was however, decided, that the subcommittee of DCC to be constituted to examine testing laboratory issues should also examine this issue.

Item No.51: Status of dietary supplements/nutraceuticals

There is an increasing trend of manufacture of vitaminized preparations as antioxidants etc. as dietary supplements/nutraceuticals with hardly any regulation under PFA, inspite of the fact that these are prescribed and sold as "Drugs". This activity requires to be put to an end by way of legislation that these should be manufactured and sold under Drugs manufacturing/sale-licence.

On this issue the Chairman informed the committee about the status of efforts being made for regulation of dietary supplement/nutraceuticals. The issue was initially examined by a subcommittee under the Chairmanship of DGHS wherein it was decided that such products shall be examined by a tripartite committee consisting of members from AYUSH, PFA and DCG(I). Later on, it was decided that instead of having a separate category, the existing regulatory mechanism for food or drug should accommodate dietary supplements by incorporating certain changes in these laws and there should not be a third category. However, both DTAB and CCFS did not find it feasible. In the meantime the AYUSH (earlier ISM&H Department) decided to pilot a Health Food Supplement Bill. Currently, the matter is again with Dept. of Health and a suitable legislation to regulate these products as a separate category is being thought of.

Since the issue is already under consideration of Govt., no decision on the matter can be taken by DCC.

Item No.52 : Standard drug formulary

The variety of permutation/combination, at times with hardly any therapeutic rationale or at times violating the provisions applicable to 'NEW DRUGS" are permitted to be manufactured which result into variation from state to state. Therefore, to bring uniformity the DCG(I) office may come out with positive list of Standard Drug Formulary, which only be refereed while permitting manufacture of formulations by State Drugs Controllers.

The issue was discussed in detail. It was realized that over the years, State Licensing Authorities have been approving drug formulations for which there is specific provision in the Rules. Unlike other countries, central registry of drug products has not been possible. Even in developed countries, there are old products which may not be reflected in their central register. This is no doubt a crucial issue. However, regrettably, many State Authorities have been permitting new drug formulations at their own level, inspite of the Rules having been amended in May 2002 to avoid any such possibility. The Chairman again emphasized the need for strict discipline and a level playing field. It is because of these deviations and non-uniformity that there is strong demand for total centralization of regulation over drugs manufacturing and marketing in the country.

DCC members were advised to give a serious thought to this issue and convey their suggestions. It was also agreed to furnish the list of drugs approved by DCG(I) to all State Drugs Controllers and informed that same would also be displayed on the website.

Item No.53 : Banning of drugs under Section 26-A

To avoid controversies, a cut-off date can be fixed for manufacturers and a future cut off date be fixed for sale of drugs which may not be earlier than its Expiry Date. This will avoid steps of recall/destruction of recalled goods etc.

Considering the difficulties experienced by the State Licensing Authorities in regulating the stocking of drugs banned under Section 26-A, it was decided that a fixed period for manufacturers shall also be mentioned in future at the time of banning the drugs under Section 26-A.

Item No.54 : Procedure for recall of drugs be codified

The procedure for recall of drugs be codified in the legislation to make the recall to be effective recall in true sense; in situations such as where adverse drug reactions are reported or batch(es) declared as not of standard quality.

DCC agreed to the proposal and decided to have the issue examined through subcommittee on enforcement matters.

Item No.55 : Levy of testing fee of samples sent by state to testing laboratories under control of Central Govt.

Such statutory samples sent by Inspectorate staff should be exempted from levy of testing fee, presently being levied by testing laboratories under the domain of Central Govt.

The Chairman informed that the fees prescribed under Schedule B of Drugs and Cosmetics Act for testing drugs is a statutory requirement and in any circumstances the levied fees cannot be exempted. After all, monitoring of quality of drugs is a prime responsibility of State Govts., who have to make necessary budgetary provisions for this activity.

Item No.56 : Change of constitution in event of death of proprietor of firm

Guidelines may be evolved as to whether this should be taken up as change of constitution of firm or the licensee has to close down its operations instantaneously sine-die the death of proprietor of firm.

During discussion the Commissioner FDA Maharashtra informed that in the event of death of the proprietor of the firm the licence shall be deemed to be valid for a period of 3 months from the date on which the event of death taken place unless a fresh licence has been taken from the licensing authority and/or Central Licensing Authority in the name of the firm with changed constitution. The inadvertent delay is being condemned by some authorities by compounding the fees though there is no specific provision. This issue may need to be examined by the subcommittee on legal matters.

Item No.57 : Failure of licensee to apply for renewal with late fee within six months period

Some of the states are compounding such matters by way of levy of extra penalties in terms of fee and few states are resorting to prosecutions in such cases. However, the compounding of such of such offences may be allowed for uniformity.

The Chairman informed that as per the statutory norms the application for renewal of the license is made before its expiry or if the application is made within 6 months of its expiry, after payment of the additional fees, the license shall continue to be in force until orders are passed on the application and the license shall be deemed to have expired, if the application for its renewal is not made within 6 months of its expiry.

Item No.58 : Regulation of sale/distribution of blood bags

To avoid misuse of blood bags by unscrupulous traders/Nursing Homes indulging in clandestine activity of blood-banking operations, the existing Rule 65 requires to be further amended, so that the sale of blood bags is made only to licensed blood banks so as to make manufacturers/traders accountable for same.

It was felt by majority of members that it is basically an enforcement issue. The present system of control over blood banks is adequate. Amending the law for certain isolated incidents may make it too restrictive. Therefore, status quo to be maintained.

Tripura

Item No.59 : Date of expiry of drugs – clarification thereof

Rule 65(17) states that no drugs shall be sold or stocked by the licensees after the date of expiration of potency recorded on the label. Again, explanation given below Rule 96 states that the date of expiry shall be in terms of month or year and it shall mean that the drug is recommended till the last date of the month. This has resulted confusion. It is, therefore, proposed that word "preceding" may be inserted before the word "Month" to remove confusion. The DCC may kindly consider the issue and take appropriate decision as deem fit.

After the discussion it was decided that the month on which the drug shall be expired is considered to be the last date of the month.

Item No.60 : Definition of professional donor of blood

In order to prevent and take action against the donation of blood by professionals, it is necessary to amend the definitions of the "professional donor" to include persons donating blood at frequent interval within a period of three months, irrespective of monetary transactions, since it is very difficult to establish transaction of money in such cases though they appear to be involved in professional donation of blood. The DCC may kindly discuss the issue so as to plugged the low fools in the system of blood donation.

After deliberating on the issue, it was felt by DCC that suitable definition, if so feasible, may be suggested by DC Tripura. However, the matter may also be taken up by the legal subcommittee of DCC.

Item No.61: Despatch of samples for tests or analysis by Judicial Magistrate to appellate laboratory

Despatch of samples for tests or analysis is related to Section 25(4) of the Drugs and Cosmetics Act, but Section 25(1) is mentioned in Rule 4 of the Drugs and Cosmetics Act & Rules, which creates confusion. It is necessary to amend the Rule to remove the confusion. The DCC may kindly consider the proposal.

Drugs Controller Tripura informed that dispatch of samples for tests or analysis is related to Section 25(4) of the Drugs and Cosmetics Act, but Section 25(1) is mentioned in Rule 4 of the Drugs and Cosmetics Act and Rules, which creates confusion. Therefore, it is proposed to amend the said rule to remove the confusion.

DCC agreed to get the proposal examined through its legal subcommittee.

E. Supplementary Agenda Items

Item No.61 (A): Labelling requirements meant for export purposes

Under Rule 94 of the Drugs and Cosmetics Rules, certain exemptions are given in respect of labeling requirement for drugs meant for export purposes. However, certain exporters are requesting for further concession in respect of labeling requirements e.g., export of finished formulation without affixing the label in the innermost containers or they will not label the drugs as per the Rules. In certain cases, requests are received to label the goods with languages other than English.

DCC may like to take a view in the matter.

Under Rule-94 of the Drugs and Cosmetics Rules certain exemptions are given in respect of labelling requirement for drugs meant for export purposes. However, certain exporters are requesting for further concession in respect of labelling requirements e.g. export of finished formulations without affixing the label in the innermost containers or they will not label the drugs as per the Rules. In certain cases, requests are received to label the goods only with foreign language.

After lengthy discussion, the members felt that in order to encourage export of drugs, we may not have any objection to give further exemption in respect of labelling of the drugs as suited to the importing countries in addition to exemption already given in Rule 94. However, the extent of exemption to be given will be decided by the competent authority. Already, even unapproved or locally banned drugs are allowed to be manufactured for export purposes. This issue may also be examined by the legal subcommittee.

Item No.62: Neutral code for export of narcotic and psychotropic substances

Under Rule 94 of the Drugs and Cosmetics Rules, drugs can be manufactured under neutral code issued by the State Licensing Authorities for export purposes. However, neutral codes are not permitted for the export of narcotic and psychotropic substances as per above Rule. This Directorate has received representation that units located in SEZ Zones (100% export units) may be allowed to export narcotic and psychotropic substances as the importing countries are permitting such imports under neutral code. The Port Officer does not permit any export or import without import/export authorization certificate from Narcotic Commissioner of India, Gwalior.

DCC may like to take a view in the matter.

Under rule-94 of Drugs and Cosmetics Rules, drugs can be manufactured under neutral code issued by the State Licensing Authority for export purposes. However, *neutral codes are not permitted for the export of narcotic and psychotropic substances as per above rules.* This Directorate is receiving representations that units located in SEZ Zones (100% export units) may be allowed to also export drugs containing narcotic and psychotropic substances if the importing countries permit such imports under neutral code. The Port Officer, however, would not permit any export or import of any narcotic and psychotropic substances without import/export authorization certificate from Narcotic Commissioner of India, Gwalior.

The members of DCC discussed the matter to allow the export of narcotic and psychotropic drugs under neutral code by the units located in SEZ zones. The DCC felt that there might not be any objection in allowing the exports of narcotic and psychotropic drugs if they are used in importing country and if they accept a neutral code. However, the members felt that since, these categories of drugs are also controlled under the NDPS Act and Rules, it would be appropriate that opinion of NCB be obtained.

Item No.63 : Extended shelf life of drugs meant for export

Schedule – P of Drugs and Cosmetics Rules specified the shelf life of a drug. However, certain foreign buyers request for higher shelf life than that prescribed in the Schedule-P. To promote exports, such requests may be considered on the basis of stability study and real time stability study of the drugs carried out by the manufacturers and duly examined by the concerned state drugs controller. The state drugs controller may issue extended shelf life certificate of drugs, which may be submitted to the concerned Port Officer for the release of consignment meant for export.

DCC may like to deliberate on the issue.

The matter relating export of drugs with higher shelf life than the prescribed in Schedule P of the Drugs and Cosmetics Rules for the purpose of export only was discussed and it was decided that in order to facilitate export, drugs with extended shelf life as may be accepted by the importing country, may be permitted on the basis of stability studies of the drugs carried out by the manufacturers and duly examined by the concerned State Drug Controller and accordingly they will issue a certificate of the drug which may be accepted by Port Officer for the release of consignment meant for export. However, this exemption will not be considered in respect of sale of drugs in domestic market where the criteria indicated in Schedule P shall be followed.

State Agenda Items

Delhi

Item No.64 : Amendment of footnote No. 2 to Schedule P of the Drugs and Cosmetics Rules, 1945

Presently, footnote to the Schedule P of the Drugs and Cosmetics Rules, 1945 reads as "*The term 'Cold Place' means a place having a temperature not exceeding 8^0 C*". However, in the general monograph of Indian Pharmacopoeia, the term 'Cold Place' has been described as any temperature not exceeding 8^0 C and usually between 2^0 C to 8^0 C. Accordingly, the footnote to Schedule P should be amended as follows:

"*The term 'Cold Place' means a place having a temperature between 2^0 C and 8^0 C*"

The DCC agreed with the suggestion of Drugs Controller Delhi in respect of amending footnote to Schedule P as follows:

"*The term 'Cold Place' means a place having a temperature between 2^0 C and 8^0 C*".
Amendment to be made accordingly.

Item No.65 : Inclusion of additional sub-clause in clause 5-B of Schedule K to the Drugs and Cosmetics Rules, 1945 with regard to blood storage center

Clause 5-B to Schedule K of the Drugs and Cosmetics Rules was inserted vide GSR 909(e) dated 20-12-2001, which related to whole

Human Blood I.P. and/public or its components stored for transfusion by a first referral unit, community health centre, primary health centre and a hospital. Vide the said amendment, such storage were exempted from the provisions of chapter IV of the Drugs and Cosmetics Act, 1940 and Rules made thereunder.

As per guideline No. 7 received from the office of the DCG(I) before permission for grant of approval for such a storage centre is granted, an inspection of the proposed blood storage centre is to be carried out by the respective said Drugs Control Department. No fees for such inspection has been prescribed under the Rules. It is suggested that an inspection fees of Rs. 1500/- as provided under Rule 122 (F) may be recommended.

Presently, there is no provision under the present set of Rules for taking action against a blood storage centre, in case some contravention of the Rules or the conditions of the exemption provided under Schedule K are violated. It is suggested that a suitable amendment in the Rules be carried out in the Drugs and Cosmetics Rules as already prescribed under Rule 122 (O) of the said Rules, regarding suspension/cancellation of approval/license.

As per guidance No. 10 provided by the office of DCG(I), the validity of the approval shall be for a period of two years from the date of approval. This clause should be amended as follows: the validity of approval shall be for a period of two years from the date of issue of the approval or the validity of the license issued on Form-28 C to the blood bank from where the blood or its components are procured, whichever is early.

While appreciating the concern expressed by Delhi Drugs Administration, a general view emerged after detailed deliberation that this provision has been recently introduced to meet a specific need. We may first have experience on the actual working of these storage centers. It was observed that so far only few storage centers have been established in the country. The chairman requested all members to provide feedback about the working of blood storage centers so as to enable us to introduce timely corrections, if so needed.

Karnataka

Item No.66 : Shelf life of rifampicin capsules

Govt. of India, vide notification No. 602(A), dated 24-8-2001 has published a draft notification for extension of shelf life of rifampicin capsules from 24 months to 36 months. It may please be noted that the

shelf life of rifampicin (raw material) is also 36 months. It will not be appropriate to assign same shelf life to finished product as that of its raw material as there will be some time laps by the time the raw material is received for its manufacture by the formulation manufacture. Hence, it is suggested that the shelf life of rifampicin capsules may be assigned to 30 months. Similar examples of this nature are also given in Schedule P. For example,

Raw Material	Shelf Life	Formulation	Shelf Life
Doxycycline Monohydrate	36 Months	Doxycycline Monohydrate Capsules	36 Months
Erythromycin Estolate	36 Months	Erythromycin Estolate for Oral Suspension	36 Months
Tetracycline Hydrochloride	36 Months	Tetracycline Hydrochloride Capsules	36 Months
Chlortetracycline HCl	60 Months	Chlortetracycline Capsules	60 Months

In these cases too, either raw material may be assigned more shelf life or shelf life of formulations may be reduced.

The Chairman informed to the members that the system of assigning shelf life to bulk drug is different in some countries. The issue of shelf life of drugs as well as bulk drugs has already been discussed in the last DCC and the proposal is under review. The enforcement committee may, therefore, examine this issue in depth and an early view to be taken in the matter.

Item No.67: Release pattern of sustained release formulations of new drugs

Whenever new drug is cleared by DCG (I), New Delhi, copy is endorsed to the concerned Drugs Controller, where the manufacturer is situated. Whenever sustained release formulations are cleared, we receive the permission letter but we do not receive the release pattern of the same product. There is a possibility that the two or more manufacturers may get clearance for the same products and they may submit different release patterns for the same products. To bring uniformity in the release pattern, it is suggested that the details of release pattern in respect of such products may also be forwarded along with the method of analysis, working/reference standard of such new drugs.

The Chairman agreed with the proposal to provide release pattern of sustained release formulations along with its method of analysis. Director, CDL, CDTL Mumbai and CIPL Ghaziabad were requested to provide the reference standards of drugs if required by a Govt. analyst at the time of

approving a new drug, which has been tested and validated in their laboratory. However, it was emphasized that in order to maintain uniformity and ensure quality, the State licensing authority should not deviate from the prescribed norms of approval.

Item No.68 : **Amendment of Rule 66 of Drugs and Cosmetics Rules**

Consequent to amendment of Rule 51 regarding number of items of inspection of sale premises, it is necessary to amend Rule 66, as at present, it is necessary that the licensee commits the same omission within twelve months before the date on which the act or omission in question took place. Under the new Rule, if the premise is inspected only once and the contravention warrants suspension or cancellation of licenses, it is not legally correct to act only on one inspection report in twelve months.

Hence, it is suggested to delete sub-section (b) of Rule 66, as similar provision is not incorporated under Rule 85.

During the discussion, the Drugs Controller Delhi explained that existing law can prevent offence and there is no need for amending the concerned rule. Commissioner FDA, Maharashtra informed that adequate powers have been conferred to the State Licensing Authorities to deal with such situations. The provision of inspection in a year does not mean that more number of inspections cannot be made if the situation so warrants.

Accordingly the DCC agreed not to delete sub-Section (b) of Rule 66.

Item No.69: Clarification regarding dietary supplements/nutritional products

Some of the manufacturers are manufacturing vitamin preparations as dietary supplements/nutritional products. The compositions of these products are for the therapeutic use and the products are being sold through medical stores. The manufacturers are approaching to the doctors to write the prescription for these products giving the technical literature wherein it has been mentioned that these products are used for therapeutic purpose. It is felt that the manufacturers are trying to circumvent the provisions of the DPCO and Drugs and Cosmetics Act by not possessing the drug license for these products. Hence, DCC may issue clarification in this regard.

Further, it may please be noted that Hon'ble High Court of Karnataka and Hon'ble High Court of Kerala have granted interim stay order in this regard in favour of manufacturers restraining the enforcement officers not to restrict the sales or distribution of such products.

Please refer to the Minutes of Agenda No. 51.

Item No.70 : Test and analysis of diagnostic reagents

Vide gazette notification No. GSR 601(E) dated 27th August 2002, the following diagnostic kits have been notified as drugs: *in vitro* diagnostic devices for HIV, HbsAg and HCV. The above notification indicates that the devices used in the detection of HIV, HbsAg and HCV are also drugs in our opinion. Therefore, it is requested to clarify whether the above interpretation is correct.

The Chairman informed to the members that as per the Gazette Notification No. GSR 601 dated 27th August, 2002, the diagnostic kits for detection of HIV, HbsAg and HCV have been notified as drugs, in so far as Section 3 of Drugs and Cosmetics Act is concerned. Since these diagnostic kits are validated in terms of specificity and sensitivity. However, the applicator/devices used in the detection of HIV, HbsAg and HCV have not been notified as drugs. It is proposed to undertake a comprehensive review of medical devices so as to introduce specific regulatory provisions in Drugs & Cosmetics Act.

Item No.71 : Clarification regarding the quantity of diagnostic kits to be sent for analysis

As per Rule 3A of Drugs and Cosmetics Act, NIB has been notified as laboratory for the purpose of analysis of diagnostic kits. It is not known how much quantity to be sent and the manner in which (whether cold chain) required while sending the kits for analysis. The same may be clarified.

Please refer to the Minutes of Agenda No. 18.

Item No.72 : Bathing bar to be included in Schedule S

Bathing bar has been considered as cosmetics. There are so many manufacturers manufacturing bathing bar. The standards has been prescribed by BIS as IS:14398-1997. However, this bathing bar has not been included in Schedule S. Since it is not included in Schedule S, quality of the bathing bar cannot be declared. Therefore, it is suggested that bathing bar may be included in Schedule S.

The Chairman informed to the members that standards for bathing bar have already been incorporated in BIS and would be included in Schedule S.

Item No.73 : **Approved laboratory in form 37**

At present, no legal action can be taken against the approved laboratory, as there is no offence clause and penal clause in this regard. Action cannot be taken against the approved laboratory in case they issue wrong report. Appropriate amendment may be made in the Act in this regard.

This issue has been discussed vide agenda item no. 3.2 of A.T.R. of 32nd DCC meeting.

Item No.74 : **Confiscation and destruction of banned drugs**

Mere stocking of banned drugs is not an offence under Section 26A of Drugs and Cosmetics Act. After the ban order if the stock is detected, it cannot be confiscated and destroyed as there is no provision in the Drugs and Cosmetics Act regarding confiscation and destruction of banned drugs. therefore, Section 33(2) may be amended as follows:

After the word "such cosmetic" add "or if the drug is banned under Section 26A of this Act, such drug" shall be liable to confiscation.

If banned drug is confiscated, then there should be provision for destruction of the banned drug. Regarding the destruction of drugs, Rule 58-A may be amended as follows:

After sub-rule (3) under Rule 58-A, the following sub-rule may be added:

"(4) With regard to banned drug under Section 26A, the court shall order the destruction of the drug. The destruction shall take place under the supervision of the inspector in the presence of such authority, if any, as may be specified by the court".

It was decided that this issue would be taken up by the subcommittee of DCC on enforcement matters.

Item No.75 : **Inclusion of *in vitro* blood grouping sera as "drugs" under section 3(b)(iv) of Drugs and Cosmetics Act**

Government of India vide notification No. GSR 600(E) dated 27-8-2002 has included *in vitro* blood grouping sera as entry at Sl. No. 10 under Schedule C(1). However, *in vitro* blood grouping sera has not been notified as "drugs" under Section 3(b)(iv) of Drugs and Cosmetics Act. Unless the same is notified under the above section, it cannot be considered as a drug. Therefore, it is suggested that *in vitro*

blood grouping sera may be notified as drug under Section 3(b)(iv) of Drugs and Cosmetics Act.

It was decided that this issue would be examined by the office of DCG(I) and appropriate follow-up action taken in the matter would be informed to the members.

Item No.76 : **Extending the time to 45 days instead of 20 days for Form-15**

Majority of the times prohibitory in Form-15 is issued whenever the quality of the product is suspected and the sample is sent for analysis. However, test report is not received within 20 days. Therefore, after expiry of 20 days, fresh Form-15 is required to be issued which is a cumbersome procedure. Hence, the period of prohibitory order in Form-15 may be extended from present 20 days to 45 days.

Please refer to the Minutes of Agenda No. 21. This issue has been discussed by DCC number of times. It is not certain that even if the period is increased to 45 days, the necessary investigation etc. would be completed. Moreover, it may require amendment of the Act. It was, therefore, decided that subcommittee on legal matters may examine it closely.

Item No.77 : **Penal clause under Section 27(b)(ii) may be amended**

The punishment for unlicensed dealer and unlicensed manufacturer is stipulated under Section 27(b)(ii) of Drugs and Cosmetics Act for violation of Section 18(C). The offence committed by the dealer under Section 18(C) should not be equated with the offence committed by the manufacturer. Therefore, separate penal clause may be prescribed for the violation of Section 18(C) by a dealer and a manufacturer.

The Chairman informed to the members that the issue requires amendments under the Act and therefore the matter has to be considered by the Ministry. Before that, the matter may be got closely examined by the subcommittee on legal issues suggesting necessary changes to be incorporated under the Act.

Item No.78 : **Recall of drugs**

Whenever the drug is declared as not of standard quality, it is intimated to the manufacturer. The manufacturer shall take the responsibility and recall the unsold stock of the drugs from the market within the specified period. In this regard, a sub-committee was constituted under special DCC and they have submitted the report. It is not known whether DCC has accepted the sub-committee

report. In case the report is accepted, the copy of the same to be forwarded for uniform implementation.

A copy of guidelines on recall of drugs have been circulated to all State Drugs Controllers.

Item No.79 : **Guidelines to intimate the action taken report against the manufacturer by the State Drug Controllers**

DCG(I) has circulated the guidelines for the action to be taken against the manufacturers whenever the products are declared as not of standard quality as per 27th DCC. These guidelines do not cover all the products, i.e., action to be taken in respect of condoms, diagnostic reagents/kits, medical devices etc. Therefore, guidelines may be prescribed for these products.

Some of the State Drugs Controllers do not intimate the action taken against the manufacturers even after 3-4 years after intimating to them. Since they do not intimate the action against the manufacturer situated in their jurisdiction, the file cannot be disposed of. We are required to intimate to accountant general, legislature, lokaukta etc., the action taken against the manufacturer of not of standard quality drugs, all the state drugs controllers may be informed to intimate the action taken against the manufacturer within six months after receiving the test reports.

DCC was informed that in the context of recommendation of Mashelkar Committee, it has been decided to review the existing guidelines on follow up action in respect of NSQ drugs. There is also a need to prepare guidelines in respect of action to be taken in cases of condoms, diagnostic kits, reagents etc. Accordingly it was decided that the matter may be got examined by the enforcement subcommittee.

Item No.80 : **Use of rapid test kits for testing of HIV and HCV in blood banks**

DCG(I) vide letter No. F.No. 18-10/2001-DC dated 29-11-2002 has addressed letter to all the State Drug Controllers informing that the rapid test kits of approved sensitivity should be permitted to be used for testing of HIV 1 & 2 and HCV. NIB is analyzing the kits and certifying about the sensitivity. It is not known whether the manufacturer or NIB or DCG(I) has to certify about the approved sensitivity of the rapid test kits to be used for testing HIV 1 & 2 and HCV in the blood banks.

Sensitivity and specificity of kits is ascertained by NIB. There has been much improvement over the years in the efficiency of rapid test kits. The present benchmarks are 98% specificity and 99.5% sensitivity.

Item No.81: **Stocking of drugs manufactured on their own and on loan license in the licensed premise for which license in Form-25 and/or Form-28 are granted**

In the state of Karnataka, the manufacturer is having manufacturing license for their own plant and they are also getting certain products manufactured on loan license mentioning their registered office address or corporate office address. Manufacturing license and loan license covers sales license. Question arises that whether the manufacturer can stock the products manufactured on loan license in the premises where license in Form 25 and Form 28 have been granted.

On this proposal, the Drugs Controller Andhra Pradesh informed that there is no violation under the Rule. However, Commissioner, FDA Goa informed that under the labeling provision, the manufacturer has to mention the name of the manufacturer alongwith its address on the label of the drug. Mentioning of registered office on the label is optional. The committee noted that the labeling provision should be strictly followed with regard to the stocking of products manufactured under loan license in the premises where license in Form 25 and 28 have been granted. It was decided that the matter may be further got examined by the subcommittee on legal matters.

Item No.82 : **Problems pertaining to drug testing laboratories**

A. **Reference standards:**

a. **Only a few reference standards are available with drug testing laboratories.**

b. **Reference standards supplied by CIPL does not carry the potency, use before date on the label.**

c. **Internal standards are very costly and not available easily.**

d. **USP reference standards are sold at s. 9000/- per molecule, which is valid only for a short time. As we receive assorted samples as against private organizations procuring these is difficult. Hence, if these are sold at a discounted price to Govt. institution, then it will be feasible.**

e. **Internal standards and impurities are not easily available e.g., ranitidine impurity B, related substances impurities for rifampicin, nor-adrenaline and others.**

Necessary steps may be taken to solve these problems.

B. Guidelines for Govt. analysts in issuing of test reports in following cases:

1. The Govt. analysts are facing difficulty, as they cannot issue a standard quality report when all the tests are not done. As a statutory body, they are being criticized for not doing complete analysis as per the requirements of the law and the whole exercise of Drugs Inspectors drawing the samples is an exercise in futility and the very purpose of drawing the sample is defeated.

   When complete analysis of sample cannot be carried out as per the monograph, they are not giving any conclusion even if a single test is not done. Therefore, it will be feasible to mention as :

   Conclusion: The sample conforms to I.P. Standards with reference to above tests only.

   Test is not done due to non-availability of internal standards, chemicals etc.

2. When sample fails with reference to description: "Description" & "Colour" are not included under "standards" in the monograph. But, they are declaring the sample as not of standard quality with reference to "description" quoting the general notices of I.P., in case of official products and Schedule V of Drugs and Cosmetics Act in case of patent and proprietary drugs.

   But in case of sample, where raw material is white and finished product is coloured, they are not sure what is to be done.

3. If the sample is failing with reference to description, whether it is required to carry out further tests: When only one container is received, question arises that whether it can be opened and further tests to be done for further analysis or should it be preserved intact.

4. Conclusion to be given in the test report: In case of official products, if the assay is carried out by a method other than the one mentioned in the monograph as facilities will not be available as per the method given in IP/BP/USP, in such cases, it can be reported to IP/BP/USP standards. Method used may be taken from the journals or manufacturers' method. In such cases it should be reported as conforms to "label claim" or "I.P. standards".

5. **In case of medical devices, they are having difficulty in carrying out all the tests as per IS standards. Many fabricated equipments are required which we are unable to get. Some of the tests are not very clear (e.g., how the bevel of angle has to be measured in case of hypodermic needles).**

6. **In case of condoms, as per Schedule R, it can be declared as not of standard quality only when it fails in (a) water leakage test, (b) bursting volume and pressure test and (c) dimensions. It is not clear what is to be done, if the sample is failing with reference to quantity of lubricant and colour fastness tests etc.**

C. <u>Request for the meetings of Govt. analysts</u>: **Regular meetings of Govt. analysts may be conducted at least once in a year to exchange ideas in order to improve the functioning of labs.**

There are large numbers of issues taken up as additional agenda. Members have therefore not been able to formulate their views. Since the issue involves the logistic problem related to procurement of reference standards, testing profile, facilities to be provided for testing of drugs and the gross observation of the results, it was decided to get the issue examined in detail by the subcommittee on laboratory matters. This would enable us to have proper guidelines on various matters pertaining to day to day working of laboratories.

With regard to Part C of the Agenda, the Chairman informed that Director, CDL, Kolkata has been advised to convene a meeting of Government analysts for this purpose.

Gujarat

Item No.83 : **Permission for new drugs by State Licensing Authority**

Recently, it was found on verification that certain letters of permission for New Drugs of Drugs Controller General (India), New Delhi were found fake. DCG (I) confirmed the same and informed that they have never issued such permission in such cases. An FIR has already been launched at Gandhinagar against such manufacturers. This type of permission/approvals issued by DCG (I) are not counter-verified and it is felt that such fake letters might have been produced in some other States.

It is therefore suggested that counter verification of such letters is necessary. This point may be deliberated and proper procedure for

future grant of permission by State Licensing Authority and counter verification be decided.

The Joint Commissioner FDA, Gujarat informed to the Chairman that recently certain letters of permission for New Drugs purported to have been issued by the office of Drugs Controller General (India), were found fake. It was therefore suggested that counter verification of such letters is necessary.

While on discussion the Chairman informed the members that the new drugs approved by the Office of DCG(I) is displayed on the website. As per new practice, the new drug permission letter is signed by 2-3 officers involved in examining the product. In case if the state licensing authority does not receive such permission letter, the same may be obtained from the Office of the DCG(I). All members were requested to provide useful suggestions in the matter so as to avoid any such possibility.

Item No.84 : Grant of Licence for Test and Analysis

(a) ***Number of products and fees*: As per the present provisions of the Drugs & Cosmetics Rules, license in form No. 29 is issued against each application. If the firm applies for total 10 products, then all such 10 products are granted under the same license. Similarly, if the firm applies for only one product, in that case also license is issued for one product. There is no clarification as to how many number of products can be granted in one license in Form No.29. There is no provision for additional fees if the products exceed in one license, therefore, it needs clarification.**

(b) ***Facilities*: At present the Act and Chapter VII of Rules is silent on the facilities to be fulfilled before granting license in Form 29. There are no licence conditions in Form No. 29 unlike other licenses. For experiment purpose, the products manufactured by the licensee are being used for human subjects in some cases, which is to be manufactured under the controlled environment especially when manufacturing parenteral products for examination, test or analysis which requires so many facilities during manufacturing to avoid any mishap. Before granting license in Form No.29, the license in Form No. 25 and 28 is a must or otherwise?**

As per discussion, it was felt that licence in Form 29 is for test and analysis etc., which is basically a research and development activity. This needs to be encouraged. Therefore, no further amendment may be made at this stage.

Item No.85 : Preservation period for reference samples

The last sentence of Rule 74(I) reads as under:

"In case of drugs where no date of expiry or potency is specified on label, the reference samples shall be maintained for a period of 3 years from the date of manufacture". However, as per the present requirements of the Rules, the shelf life is required to be mentioned on all the products. Thus there is no drug which does not bear any expiry date on the label.

In view of the above, it is felt that the last sentence of Rule 74(I) as stated above is required to be removed. This sentence also appears in other Rules which are also required to be removed.

The proposal was agreed in principle. However, it was decided that the proposal should be examined by subcommittee on laboratory matters for suggesting specific amendment.

Item No.86 : Grant of WHO GMP Certificate to loan licensees

At present WHO GMP certificate is given to loan licensees by the State Licensing Authority if the applicant firm provides details such as Master Card and if it is identical with the parent firm in respect of the products applied for under the WHO GMP Certificate. Moreover, the applied product is also manufactured by the parent firm and it is in the list of products approved under WHO GMP certificate. However, there is no uniform policy and hence the same may be discussed if the Drugs Controlled General (India) feels that the involvement of CDSCO Zonal Officer is required.

After the discussion, view which emerged was that the basic requirement for issuing WHO GMP certificate is to be complied by the Licensee including loan licensee. Since it is felt that there is lack of uniformity in this regard, the subcommittee on enforcement matter may examine this issue and suggest appropriate norms.

Item No.87 : Preservation of Records

As per Rule 78 (c)(ii), test records are required to be preserved for 2 years from the expiry date. Whereas as per Rule 124 of Schedule M, the records are to be retained for 1 year after the expiry date of the finished product.

Thus the period for the preservation differ for the same records, which are required to be the same.

After detailed deliberation, it was agreed that the general requirements speaks about the basic records of the product like SOPs, Drug Master File, Batch Manufacturing Records etc. Whereas, Rule 78 (c)(ii) speaks specifically about the test records and therefore it is mandatory for keeping test records for 2 years from the expiry date. Therefore, status quo may be maintained.

Concluding Remarks and Vote of Thanks

Summing up the two days discussions, the chairman reminded the members that individually and collectively, they carry a heavy responsibility of ensuring quality and safety of drugs to every consumer in the country. They have to keep themselves abreast of latest changes and innovation in the field of pharmaceutical sciences and regulatory strategies. They have also to provide level playing field to the industry and trade. It is hoped that subcommittees of DCC would undertake a serious examination of the issues referred to them and would assist the DCC as well as policy makers in improving the drug regulatory scenario in the country. He thanked all the members for their participation and contribution to the deliberations.

The meeting ended with thanks to chair.

Subcommittees of DCC

During the course of discussion in the 35th DCC meeting, it was felt that member of regulatory/technical issues require a closer and in-depth examination by expert sub-groups of DCC. Accordingly, composition of different sub-committees was deliberated and it was decided to constitute following four sub-committees:

1. Subcommittee on legal issues
2. Subcommittee on enforcement issues
3. Subcommittee on drug testing laboratories
4. Subcommittee on medical devices.

The office of DCG (I) would request the convener of these subcommittees to deliberate on specific issues, which have been identified by DCC. The convener would arrange for the meeting and would finalize the recommendations of the subcommittee for consideration of DCC. Any other expert, as deemed appropriate, may be co-opted by the subcommittee or its convener. After eliciting response from the members, the constitution of various subcommittees was decided as under:

1. Subcommittee on legal issues

Commissioner, FDA, Maharashtra

Convener

DC Delhi
Member

DC Rajasthan
Member

Director, FDA, Goa
Member

DC Kerala
Member

Law officer, Office of DCG(I)
Member

Issues to be examined:

Item No. 24(34th DCC), 4 {para 2.10 (i), 2.10 (ii)}, 20, 21, 22, 36, 42, 47, 56, 60, 61, 61(A), 76, 77, 81.

2. Subcommittee on Drug Testing Laboratories

Director, CDTL, Mumbai
Convener

Jt. Commissioner, Drug Lab, Gujrat
Member

Incharge of Drug Testing Lab, Tamil Nadu
Member

Incharge, Drug Testing Laboratory, FDA, Mumbai
Member

Incharge, Drug Laboratory, Karnataka
Member

JDC(I) NZ
Member

Issues to be examined:

Item No. 30(34th DCC), 50(34th DCC), 4 (para 4.7), 85.

3. Subcommittee on Enforcement Matters

Commissioner, FDA, Gujrat
Convener

Representative of FDA Maharashtra
Member

DC Andhra Pradesh
Member

DC Uttar Pradesh
Member

DC West Bengal
Member

DC Karnataka

Member

DC Orissa

Member

Representative of DCG(I) - DDC(I) WZ

Member

Issues to be examined:

Item No. 4{para 2.9 (i), 2.9(ii), 2.11, 3.6}, 5, 9, 23, 25, 31, 34, 45, 46, 49, 54, 66, 74, 79, 86.

4. Subcommittee on Medical Devices

To be constituted by DCG(I) in consultation with Director General of Health Services, Govt. of India.

Issues to be examined:

Item No. 1(33rd DCC), 4 (para 3.5), 44

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