**MINUTES OF THE 36TH MEETING OF THE DRUGS CONSULTATIVE COMMITTEE HELD ON 23RD AND 24TH JUNE, 2005 AT INDIA HABITAT CENTRE, NEW DELHI**

## INAUGURAL DELIBERATIONS

36th meeting of the Drugs Consultative Committee (DCC) was inaugurated by Hon'ble Dr. Anbumani Ramdoss, Union Minister of Health and Family Welfare. Shri Prasanna Hota, Secretary Health and FW, Government of India, Dr. S. P. Agarwal, Director General of Health Services and Chairman of Drugs Technical Advisory Board (DTAB), Ms. Rita Teaotia, Joint Secretary (Health) and Shri Rajesh Bhushan, Director (Drugs) were other distinguished invites which participated in the proceedings of the meeting.

Shri Ashwini Kumar, DCG(I) welcomed the Hon'ble Union Health and Family Welfare Minister and the senior officials and members of DCC. He appraised the distinguished gathering that the challenges faced by the Indian drug regulatory system due to the growing public expectations are rising. International harmonization, development of stricter benchmarks of safety, efficacy and quality, introduction of third generation drugs and delivery system, rapid growth of industry and trade, the media reports about prevalence of spurious and banned drugs in the Indian market and the multi-dimensional nature of enforcement work required high degree of skill and expertise to regulate control over the quality of drugs. He acquainted the members about the keen interest being taken by Hon'ble HFM to revamp India's drug regulatory system and to transform it into a world – class outfit.

The committee has a large agenda for discussion. Apart from the review of the workshops conducted, computerization and networking and audit of testing laboratories, other issues to be considered in the current meeting of DCC, are introduction of GLP norms in the Rules for drug testing labs, labeling requirement for cosmetics, import registration of cosmetics, control over medical devices, recommendation of Mashelkar Committee, improper approval of drug formulation by State licensing authorities etc.

He then on behalf of all DCC members conveyed their gratitude to the Union Health Minister, Secretary, Health & FW and other distinguished guests for their participation in the meeting and sharing their views as well as for providing vision for improving the drug regulatory system in India and requested the Hon'ble Health Minister to elaborate the meeting.

Hon'ble Dr. Anbumani Ramdoss, Union Minister of Health and Family Welfare, in his address stated that health is a lifetime concern of every citizen around 7the world for which, access to safe, effective and quality drugs is of paramount importance. The drug regulatory system which is required to address these drugs related concerns of the society has to be a dynamic and evolving mechanism.

Fifty years back, the indigenous Pharma industry was virtually insignificant and its pace of growth was very slow, but now it has captured around seventy per cent of market share as compared to MNCs. India is now ranked as the fourth largest producer of drugs in the world by volume. Drugs manufactured by Indian Pharma industry are increasingly being accepted all over the world, including the developed countries, because of their competitive cost while maintaining the contemporary standards of quality. We have achieved huge progress in the field of Pharma industry but our regulatory system is far behind, so there is a huge responsibility. Lot of progress is required to be made. We have to keep pace with the international developments. He emphasized that with quality he meant quality of enforcement. For the last one year, the problem of spurious drugs and substandard drugs has repeatedly been discussed in the Parliament and it is questioned whether the regulatory system is really effective and whether the steps taken so far to improve it are in the right direction. We need lot of changes. We have to be serious.

He further stated "We have commitment", a social commitment to the country. We need changes in food sector, medical education sector, communicable diseases programme and rural health sector. We have National Rural Health Mission and this is the biggest programme for the last 50 years in the health sector. The Prime Minister has stressed the need for a lot of development in health sector and Pharma industry. Like US FDA we should also form an independent and professionally sound authority."

"Today, testing of drugs samples is only about 36,000 for a huge country like ours. Some States test 5000-7000 samples whereas in some other states it is only 500. We are going to change the things and make the necessary changes happen. This is a commitment. Mashelkar Committee has put number of proposals / recommendations. There are practical problems also. You are going to deliberate on all these aspects. Then, there is the issue regarding labeling of cosmetics and claims made for these products, control over medical devices etc, uniform enforcement of GMPs, GCPs and GLPs, Schedule Y and clinical trials."

Hon'ble Minister also informed the participants about his recent visit to USA where he had personal discussions with the senior officials of US FDA. He indicated about possibility of an effective dialogue with FDA USA. He

emphasized that there must be proper enforcement of these rules and regulatory policies because if anything bad happens, then it brings a bad name for the system as a whole and leads to serious apprehension in the public mind about its competence. He further emphasized that there is lot of work to be done and rapid progress to be made. “We are not to plan for just five years but for the next fifty years. We have to keep a long-term vision and imbibe best of the practices.”

Shri Prasanna Hota, Secretary (Health & Family Welfare), Govt. of India, in his address, stated that “Hon’ble Minister has given lot of valuable directions which are really practical. We should deliberate upon them seriously. This task can be a roadmap of action towards the goal. My personal view, which I would like to share, is that we must take the task as a challenge. What is the level of skill we have. What skills we are going to achieve in the next few years? There is a tremendous gap. We have the directions from the Hon’ble Minister. You are the core group. You are the resource persons. All of you form a pool of resource. You are the instruments of society and the government. You have to rise above narrow consideration. Majority of you people are from the Pharma background. For other skills, whenever needed, we have to involve other resource persons and research institutions.”

“In the capacity building project, we are looking for fiscal issues and infrastructure. As resource persons, DCC members should give specific suggestions on the project. Man came out of jungle by thinking and not by despair. Everything cannot happen in one go. We need dedicated and continuous effort. Our country is capable beyond the manufacturing sector and the regulatory sector can also come up. What can be achieved by the involvement of other departments of the Govt. of India? We will have to see what science and technology can do in our endeavor? Knowledge / resources are to be pooled. Sophisticated regulatory authority is the fundamental need of the hour. Let this group take up the most challenging task. Let us put all out efforts and we will achieve the goals positively in one year. Let us take up the task very seriously.”

The Director General of Health Services, Dr. S. P. Agarwal, who is also the Chairman of the DTAB, highlighted the changes, which have been brought about in the Drugs and Cosmetics Rules in last few years, as a consequence to the deliberations of DCC and the DTAB. By its magnitude, these changes should herald a transformation in the drug regulatory system of country. Such significant changes had perhaps not occurred in last twenty years.

He asked the members to keep in view the directions given by the Hon’ble Health Minister and the Secretary Health, and to take them seriously. We need to achieve the kind of expertise and growth as is expected from a technically sound

and progressive regulatory system. Quality and uniformity of enforcement has to be the uppermost in mind of all members while deliberating for two days on large number of drug regulatory issues.

## ACTIVITY REPORT IN RESPECT OF DISSEMINATION OF INFORMATION

Joint Secretary, Smt. Rita Teaotia initiated the Dissemination of Information Workshop which covered the Project of Computerization and Networking of State Drugs Control Administrations and CDSCO as well as training programmes under the Capacity Building Project.

### Training Programme

Shri Rajesh Bhushan, Director (Drugs), initiated the discussion on Capacity Building Project funded by World Bank for construction / up-gradation of Drug Testing Laboratories and supply of drug testing equipments as a part of augmentation of Drug Testing facilities in the country. He requested all the stakeholders to co-operate in completion of the project.

### Technical audit report on Select Laboratories for Upgradation of Testing Facilities BY A. P. JAIN, Ex. Director Grade – 1, Director Quality Assurance, Ministry of Defence, New Delhi

Shri A. P. Jain, Consultant made a presentation on Good Laboratory Practices for up-gradation of testing facilities in the Drug Testing Laboratories in the country.

Qualification Profile of Analysts

| S. No. | Qualification | Percentage |
|---|---|---|
| 1. | B. Sc/ B. Pharma | 84.80% |
| 2. | M. Sc/M. Pharma | 15% |
| 3. | PhD | 0.20% |

- As most of the Analysts are B. Sc (72%) and are of the Age Group of 40-50 years, they lack motivation due to poor promotional avenues. Generally, wherever I visited, the Drug Analysts were disheartened and complained that their counterparts in field staff have quicker promotions in comparison to them.
- In DCL, Bangalore, the staff recruited was generally with Pharmaceutical background and 65-70% of the Analysts are women. This laboratory is generally managed by women efficiently and effectively.

- In DCL, FDA Maharashtra, the laboratory staff was found to be generally well qualified in the field of pharmaceutical sciences and percentage of computer Age Profile.

| Age Between (Years | | | |
|---|---|---|---|
| **20-30** | **30-40** | **45-50** | **50-60** |
| 10% | 25% | 50% | 15% |

- As most of Analysts were B. Sc (72%) and were of the Age Group of 40-50 years, they lack motivation due to poor promotional avenues. Generally, whenever I visited, Drug Analysts were disheartened and complained that their counterparts in field staff have quicker promotions in comparison to them.
- Due to ban on recruitment, no fresh blood has been inducted in most of the laboratories for the past 15-20 years.
- As revealed by the above table, 50% staff is between the age group of 40-50 years which were not-motivated enough as they were not promoted to the next higher grade even after 20 years in the lower scale.
- DPCs were not held regularly and in one case, no DPC was held even after 15 years.

  Staff Position in Different Testing Laboratories

| **Sl No.** | **Name of the laboratory** | **Sanctioned Post** | **Vacant Post** | **% of Vacant Post** |
|---|---|---|---|---|
| 1 | CDL, Kolkata | 146 | 19 | 13.0% |
| 2 | FDL, Baroda (Vadodara) | 72 | 16 | 22.2% |
| 3 | FDL, Mumbai | 64 Positioned | | Satisfactory |
| 4 | DTL, Lucknow | 9 | 3 | 37.5% |
| 5 | DTL, Patna | 25 | 6 | 42.9% |
| 6 | DTL, Haryana | 26 | 6 | 40% |
| 7 | DTL, Punjab | 35 | 11 | 45.8% |
| 8 | FDL, Bhopal | 28 | 2 | 11.8% |
| 9 | DCL, Bangalore | Satisfactory | | 10% |
| 10 | DCL, Chennai | ------ | ------ | 25% |

- Post of Director is vacant since 1991 and 2 posts of Deputy Directors since 1989 and 1997.

- Govt. Analyst post is vacant since 1999. Strength of Analysts has decreased whereas the strength of Drug Inspector has been increased from 15 to 30.
- Migration of Analysts from Testing Laboratory to Drug Control Administration in Tamil Nadu as a Drug Inspectors after completing 3 years in service. This has resulted in a shortage of approx. 25% of Analysts in the Laboratory.
- Work Study is conducted by the State Governments after every 5 years and the Analysts Posts may be increased or decreased keeping in view the workload.

Budgetary Provisions

| Sl. No. | No of Labs | Budget Sanctioned (Rs) / Year |
|---|---|---|
| 1 | 1 | 1-25,000 |
| 2 | 4 | 25,001-50,000 |
| 3 | 1 | 50,001-100,000 |
| 4 | 2 | 100,001-500,000 |
| 5 | 2 | 15-20 lacs & above |

- It is observed that the budgets provided to various laboratories are grossly inadequate to perform their statutory functions.
- In one of the laboratories, the technical provision committee meeting under Deputy Regional Director could not be held for the last 3 years, due to which no chemical could be procured.

Training

- NIPER identified as a training institute has already conducted 15 training programs. The module prepared for training is inadequate in the following aspects"
- The training does not include Microbiology testing techniques and no practical training in Microbiology is imparted. If NIPER does not have facilities for Microbiology training, then some alternate provision in another institute of repute should be made.

- Training on detailed GLP and requirements of IS / ISO/IEC-17025 is also locking.
- No training course has been designed for Directors of the Laboratories / Drug Controllers of the States. A short course of 5 days should be designed for them on latest techniques on Quality Control like 6-Sigma, Computerization and Higher Management

Skills. The latest trend in production like Zero-Defect Technology, Latest Dosage Forms and Pharmacovigilance may also be covered. This will also give them compulsory official break from their routine work.

Reference Standards/Materials

- Most of the laboratories have no Standing Operating Procedures for the maintenance of Reference Standards
- Reference Standards were not stored under the prescribed controlled conditions
- Reference Standards whose expiry date was over, still used for testing / analysis
- The working standards received from manufacturer were not validated for their accuracy / claim
- Reference Standards like Vitamin B1, Ascorbic Acid, which were more than 10 years old, were still used for testing
- Reference Standards were not supplied regularly by the Authorised Agencies.

Equipments

- The following critical equipments were lacking in 4 of the laboratories visited
    - Disintegration Apparatus
    - Dissolution Test Apparatus
    - pH Meter
    - Auto-Titrator
    - Potentiometer
    - UV-Spectrophotometer
    - IR-Spectrophotometer
- Samples were declared of standard quality without performing identification test, disintegration / dissolution tests on tablets, capsules
- The samples were tested for assay by non-official colorimetric method
- In some laboratories, equipment supplied from Central Govt. help were not even installed after 2 years
- In one of the laboratory, the equipment supplied was still in the packed condition.

Microbiological testing

- In all the labs, plates are not exposed to find out the bio burden in the sterility room to ensure Clean Room requirements of 10,000
- Laminar Bench has not been calibrated / validated regularly or no AMC is awarded to OEM for its maintenance.
- In most of the labs, no biochemical tests are performed to ensure viability of the organism or the strain may not have become mutant.
- In most of the labs, no SOP for maintenance, preservation and disposal of micro-organism has been prepared.
- In all the labs, analysis were not aware that UV tubes are required to be changed after a burning of 1000 hours.
- No record about the traceability of the organisms used in the microbiological assay in maintained.

Validation / Calibration of Test Equipments

- 40% of the labs visited did not have any knowledge about the validation / calibration of test equipments
- 60% of the labs had not prepared any calibration manual of equipments
- In 90% of the labs, calibration of equipment was not done by following compendia methods
- In 90% of the labs, IR Spectrophotometer, Dissolution Rate Apparatus and GLC were not calibrated
- Stop Watch and ordinary scales etc were not calibrated due to which samples declared either sub-standard or of standard quality is doubtful.
- Every lab should prepare a calibration manual for each equipment and carry our calibration periodically to ensure accuracy of equipment

Samples Declared Sub-standard / Spurious – A comparison of 6 Laboratories

| Laboratories | Total of Samples tested | Pending | Samples found sub-standard / spurious | (%) of Sub-standard / spurious drugs | Samples Analysed per Analyst / month |
|---|---|---|---|---|---|
| CDL, Kolkata | 2183 | 331 | 273 | 12.5% | 15 |
| DTL, Lucknow | 1039 | 10634/4000 | 170 | 16.4% | 15 |
| DTL, Patna | 958 | 556 | 54 | 5.6% | 18 |

| | | | | | |
|---|---|---|---|---|---|
| DTL, Haryana | 3655 | 1415 | 154 | 4.2% | 22 |
| DTL, Punjab | 1913 | 1574 | 170 | 8.9% | 27 |
| FDL, Bhopal | 2005 | 4780 | 93 | 4.6% | 15 |

- 4000 samples drawn by Drug Inspector could be not be tested due to paucity of staff / equipment / chemicals
- On an average, 8.7% drugs were found sub-standard / spurious

General

- In most of the labs, the premises of the labs required repairing / painting etc
- Documentation, matters of SOP, validation of equipment, raw data, standardization of the solution/reagents etc were poor.
- The concept of Quality Manual was found to be lacking except at FDA Maharashtra, FDL Vadodara, FDL Bhopal and CDL Kolkata.
- Most labs lack proper storage of samples under controlled conditions
- Internal audit systems do not exist
- Reference Books like BP, USP and Journals are lacking
- Housekeeping is extremely poor

Recommendations

**Functioning of Drug Testing Laboratories**

- The status of Govt. Analyst varies from Laboratory to Laboratory and they have been given junior scale in comparison to field staff. Some of the examples are as under:

| S. No. | Name of the laboratory | Designation of the laboratory in-charge | Equivalence with field staff |
|---|---|---|---|
| 1 | DCL, Bangalore | Superintendent | Deputy Drugs Controller |
| 2 | DCL, Chennai | Govt. Analyst | Joint Drug Controller |
| 3 | DCL, Mumbai | Asst. Director | Deputy Drugs Controller |
| 4 | DCL, Bhopal | Govt. Analyst | Deputy Drugs Controller |

| | | | |
|---|---|---|---|
| 5 | CDL, Kolkata | Director | Drug Controller |
| 6 | RDTL, Guwahati | Director | Deputy Drug Controller |
| 7 | DCL, Lucknow | Govt. Analyst | Drug Inspector |

- The status of Govt. Analyst be rationalized and brought at par with Joint Drug Controller of the State. They may be designated as Director to have uniformity.
- The Promotional avenues of Field & well as laboratory Staff should be same
- Failure to perform the Statutory Functions by a Central / State Drug Testing laboratory
- Labs which, due to paucity of staff, lack of equipment and insufficient infrastructure etc., are not able to perform their statutory functions as revealed by the various technical audits, no samples be sent to them for one year or till they improve their functioning
- The clearance be granted by DCG (I). Similarly, the licensing authorities should also withdraw from private testing laboratories, who do not meet the GLP requirements.
- In view of the technical audit carried out by the undersigned and 2 technical audits conducted on the directions of DCG(I). it is recommended that 5 regional labs be created for testing of drugs and smaller labs like Haryana, Punjab, Chandigarh (UT), Himachal Pradesh & Delhi be merged together to create better infrastructure
- Similarly, regional drug testing labs in different regions be created / strengthened

| Sl No. | States | Location of RDTL |
|---|---|---|
| 1 | Haryana, Punjab, Himachal Pradesh, Delhi, Chandigarh | RDTL, Chandigarh (New Laboratory is under Construction) |
| 2 | Orissa, Bihar, Assam, West Bengal, Arunachal Pradesh, Jharkhand, Sikkim | RDTL, Guwahati / DTL Kolkata |
| 3 | Uttar Pradesh, Rajasthan, Madhya Pradesh | RDTL, Delhi |
| 4 | Maharashtra, Goa, Chandigarh | CDTL / FDA, Mumbai |

| | | |
|---|---|---|
| 5 | Tamil Nadu, Pondicherry, Kerala, Andhra Pradesh, Karnataka | RDTL, Chennai |

**Formation of an Organized Service**

- A "Civil Quality Assurance Service" on the pattern of Defense Quality Assurance Service be formed with Secretary (Health) as cadre controlling authority. These officers should be positioned in different RDTLs / State Labs with a maximum tenure of 5 years in one lab.

**Filling – up of Vacant Posts**

- The vacant posts in the labs should be filled – up on top priority and the analytical staff in the country be declared as essential service

**Renewal of Drug Licence by Licensing Authorities**

- The licensing authorities, while issuing a Drug Licence for a patent and proprietary medicine or when the drug licence is renewed, the validated test method from the manufacturer must be obtained which may be sent to the state laboratory

**Conclusion**

- CDL Kolkata, FDA Maharashtra, FDL Madhya Pradesh & CDTL Mumbai, FDA, Gujarat has already prepared their Quality Policy & Quality Manual. It is hoped that the documented quality system will be implemented by them within 3-4 months. The work done by these laboratories is commendable and they have generally become eligible to apply for NABL accreditation.
- DCL Karnataka, DCL Chennai will also be able to prepare their Quality Policy & Quality Manual within 6 months.
- Shortcomings in some of the labs are very serious and the testing in those labs be suspended till they remove the deficiencies and improve their functioning.

**(A) The project of computerization of Drug Control Organizations.**

A review of Project of Computerization was made under the chairmanship of Smt. Rita Teaotia Joint Secretary, MOH & FW.

Various issues relating to data entry works, hardware & software problems of the States were deliberated. The following points emerged:

1. Hardware - Supply and installation completed at all locations
   Acceptance received from all location
2. Networking - Equipment received at all location
   - Installation completed at all location except Ranchi, Patna, Kolkata
   - Acceptance received from all locations except Ranchi, Patna, Kolkata
   - Relocation also done at Delhi State office due to Shifting
3. Application - Installed at all locations Software
   - Implemented at Hyderabad, Chennai, Shimla, Bangalore, Agartala, Raipur, Dehradun, Port Blair, Shillong, Pondicherry, Chennai Lab, CDL, Kolkata & CDTL Guwahati
   - Pending for want of regular sites / networking / data entry in most states.
4. Training - Conducted at all locations except Mumbai & Ranchi
5. Data Entry software- Installed at all locations and Data Entry started at all locations
   - Data Entry completed at Hyderabad, Chennai, Shimla, Bangalore, Agartala, Raipur, Dehradun, Port Blair, Shillong & Pondicherry
   - Balance license quantity not know except at West Bengal, Bihar, Orissa, Uttaranchal
6. Problems Faced – Non-sparing of staff for training
   - Non-availability of sites at some locations.
   - Non-availability of STD / Telephone facilities at most locations
   - Non- availability of data on Manufacturing / sales licenses
   - Limitations of Data Entry during Office Hours only
   - Lack of insistence on producing licenses / Reports only on Computer
   - Numerous suggestions for local customization by states.

It was brought out that action has been taken on the recommendations of the meeting taken by JS (RT) on the 8th February, 2005.

Each state / location wise status of Hardware i.e. Server, Nodes and data entry work i.e. actual no. of Manufacturing and Sales licenses entered and no. of persons attended the training were also highlighted during the above presentations.

The issues relating to status of data entry works, software & hardware problems etc of the various States were deliberated in the meeting and the action to be taken the various States was decided as under:

| S. No. | Location | Issue discussed | Action to be taken |
|---|---|---|---|
| 1 | Maharashtra | Additional Hardware, Software is required for other locations of the state. | State will provide fund locally. |
| 2 | Bihar | As reported by Drugs Controller, Bihar the hardware has been taken away by the State AIDS Control Cell.<br>Some data entry work is still pending | A letter from JS (RT) to be sent to Health Commissioner, Bihar for the above issue<br><br>HSCC to complete within 2 week time. |
| 3 | Punjab | UPSs are not working and no person visited since 30.09.2004. Problem facing in Software Application. | HSCC to resolve by 5th July, 05. |
| 4 | Orissa | 2 CPUs / Desktops are not working | HSCC to attend. |
| 5 | West Bengal | Shifting to the new building.<br><br>Pending data entry work.<br>Requirement of further training. | State to organize this by August, 05.<br>HSCC to organize for this. Although sufficient number has been trained, HSCC will |

| S. No. | Location | Issue discussed | Action to be taken |
|---|---|---|---|
| | | | organize further training. |
| 6 | Himachal Pradesh | Problem for accessing software due to non-availability of password. | HSCC to organize by 10th July, 05. |
| 7 | Delhi | Some data entry work is pending for sales licenses. | HSCC to train local staff for data entry. |
| 8 | Goa | Some data entry work is still pending including 30 manufacturing licenses. | HSCC to completed pending manufacturing licenses and training may be given to the personnel for the sales licenses. |
| 9 | Andhra Pradesh | Non working of the servers. | HSCC to get it rectified if not already done. |

It was clarified by HSCC that the pending data entry work is of two kinds:-

1. For new licenses
2. For extension of license or endorsement or any other change.
   While the first will require data entry of the license through data entry software, the latter can be entered only by recalling the old license data and updating it through online application software and not the data entry software.
   It was also clarified that since in future also the sales license data will be captured only through data entry module, necessary training for the same will be given to personnel concerned during re-implementation.

It was decided that all pending data entry for manufacturing licenses must be completed by 15th of July, 2005 so that implementation can be completed in all location by end of August, 2005.

**(B) Training Programme under Capacity Building Project**

JS (RT) informed all the participants that training under Capacity Building Project is going on at NIPER, Mohali, as per schedule already circulated to all State Drugs Controllers. Training is carried out in the last week of every month. She requested all the State Drug Controllers

to ensure that they depute their officers for such training well in advance as per the training calendar, which is already with them.

JS (RT) also informed the participants that at the request of the Industry personals particularly from East and South India, it has been decided to have tow training programmes during the year away from NIPER at Bhuneshwar in July, 2005 and at Kochi in September, 2005 keeping in mind that it takes quite some time for industry personals to travel to NIPER. Besides the above training programmes she informed that two workshops, one far senior Drug Regulatory Officers sometime in September and another one far Govt. Analysts sometimes in November, 2005 will also be held at NIPER during the year.

JS (RT) further emphasized that all State Drugs Controllers should ensure to nominate their officers well in advance.

Director NIPER, Dr. Rama Rao, gave a detailed presentation on the structure and progress of Training Project. It was clarified that the details of whole years training programme has already been circulated to State Drug Controllers. They should plan in advance about the nomination of concerned officers and pursue the matter with concerned authorities, wherever so required. It was also mentioned that NIPER would have to make arrangement to ensure that practical training on equipment (including calibration of the same) is provided in their training modules. NIPER would have to make arrangement to introduce mock audits of drugs and pharmaceuticals firms for participants in their training modules. In this regards DCG(I) would assist NIPER.

**Action – CDSCO North Zone, NIPER and all State Drug Controllers.**

**(C) Augmentation of Capacities of Drug Testing Laboratories.**

HSCC representative provided up to date information in respect of equipments, which have already been provided to various laboratories and those, which are in pipeline. It was decided that all necessary assistance to be provided to State authorities to enables installation of equipments and issue necessary certificates as and when these equipments have been received.

All concerned laboratories have to send up to date information in this regards.

**Action – Govt. Laboratories**

2. **CONFIRMATION OF THE MINUTES OF THE 35TH DCC MEETING HELD ON 29TH & 30TH APRIL, 2004.**

The committee unanimously agreed to the minutes of the 35th DCC meeting held on 29th & 30th April, 2004.

3. **CONSIDERATION OF THE ACTION TAKEN REPORTS RELATED TO EARLIER DCC MEETINGS**.

The Committee noted the action taken on the recommendations made by DCC in its 35th meeting held on 29th & 30th April, 2004. The Committee also noted that considerable progress has been made on most of the issues and that some of the issues, which are still being pursued, have been taken up as specific agenda items in the meeting.

4. **CENTRAL AGENDA ITMES**

**AGENDA NO. 1**

**CONSIDERATION OF PROPOSAL FOR AMENDMENT OF RULE 148 OF DRUGS AND COSMETICS RULES, 1945 GIVING INFORMATION ON THE LABEL OF THE COSMETICS ESPECIALLY BABY PRODUCTS IN RESPECT OF INGREDIENTS AND MENTIONING OF CAUTION / WARNING IN USE OF SUCH COSMETICS AND ONLY AUTHENTICATED CLAIMS TO BE INDICATED ON THE LABEL**

**Recently a view has been taken by a State Drugs Control Administration that some of the label claims for products like baby oil, baby hair oil, baby lotion, baby milk lotion, baby cream etc., may be misleading and this amount to contravention of Section 17 C (c) of the Drugs and Cosmetics Act, 1940, in the sense that these are misleading. Certain baby oils marketed carry statements like 'ideal massage for your baby' and 'daily massage has clinically shown to benefit overall growth and development' which may not have been fully authenticated. These issues were widely reported by media, even to the extent of misquoting the Commissioner, FDA, Maharashtra that the ingredients are carcinogenic. The matter was also raised in the Parliament and Hon'ble Union Minister expressed his concern about the status of he enforcement over cosmetics under the**

**provisions of Drugs and Cosmetics Act and Rules. Issues concerning cosmetics, however, need to be examined in the context of International practices. In the context of overall issue, it is proposed to amend the labeling provisions under Rule 148 of Drugs and Cosmetics Rules to the effect that all ingredients in a cosmetics product would require to be mentioned on the labels in descending order.**

**Further, as the baby products are supposed to be used on the tender skin of the infants, it may be deliberated whether a safety warning and only authenticated claims should be made on the labels for the information of the consumer.**

Issues concerning labeling of cosmetics under existing provision of Drugs and Cosmetics Rules, 1945 as well those prescribed under BIS Standard the prevailing international practice, claims made in respect of functional properties of different categories of cosmetics, their safety aspects etc. were discussed in detail by the members of DCC.

Representative of BIS Dr. Vijay Malik gave a detailed account of the modalities followed by BIS in evolving standard, including labeling requirements, for different categories of products which are then enforced by State Drugs Controllers. In the recent past, it was made mandatory to mention critical ingredients on the label i.e. those ingredients, which mainly provide intended functional property to a cosmetics.

She informed that India is perhaps the only country which has developed detailed standard for 28 categories of cosmetics products through its Cosmetics Sectional Committee of which DCG(I) is the Chairman. Some of the standards like that of kumkum, bindi, henna are unique to the country.

It has also been laid down that the ingredients used for manufacture of cosmetics have to be those listed internationally as generally recognized safe. There is also a list of ingredients which though permitting the use in country, are restricted in certain condition or use is also prescribed. BIS has published standards on number of cosmetics ingredients. After detailed deliberations Committee was of the view that many times, the enforcement staff is not aware of the labeling requirements recommended under BIS standards. Also, there is a need of harmonization in regard to the manner in which ingredients of cosmetics should be listed on their labels. Therefore, in Rule 148 the following conditions should be prescribed:-

1. Full ingredients listing – A full list of ingredients must be given in descending order of their strength on outer packaging headed by the word “INGREDIENTS”. Where there is not out packaging, list must appear on the immediate packaging. The list must-
    - Use the name given in the international nomenclature for cosmetic ingredients.
    - Show all ingredients in descending order of weight.
    - Ingredients in concentration of less than 1% may be listed in any order after those in concentration of 1% or more.
    - For decorative cosmetics, all coloring agents used in the range may be listed preceded by the word “may contain”.
    - “use before ” date.
    - Condition for use and warnings.
    - Solvents or carriers for perfumes and aromatic compositions are excluded from labeling requirements.

    At this stages the Committee also discussed the issues raised by FDA, Maharashtra as explained in Agenda 44 (1&2) in respect of **“evolving standards for cosmetic products and regulation of tall claims made by cosmetics manufacturers- “evolving standards for cosmetic products to be branded as baby cosmetic products”.** The Committee was of the general view that the amendments requiring listing of the all ingredients and labeling of caution etc. would enable a major shift suggested in respect of the desired direction. The Committee further observed that the standards for cosmetic products as well as the raw material are already in place. Also, microbiological contamination limits have been prescribed in the country for all cosmetic products including baby products. The requirements of dermatological safety, wherever so required has already been prescribed under BIS Standards.

    Issues concerning the way the cosmetics are being advertised in respect of their functional properties or benefits to the consumers as well as positioning of various cosmetics on a gender basis or on age groups basis like Baby products etc., involves broader issues, which have to be closely examined in the context of international practices, claims permitted in other countries and expectations of consumers etc. It was decided that a broad based Committee may be constituted to examine these issues. The members of the Committee should consist of –

    1. Representative of Bureau of Indian Standard.
    2. State Drugs Controller of Maharashtra, Delhi (Shri P.P. Sharam) and West Bengal.

3. An expert in cosmetology.
4. Representative from Indian Cosmetic manufacturers Associations.
5. Representatives of Department of AYUSH.
6. Representatives from Advertising Council of India; and
7. A representative of CDSCO

Meeting of the expert committee would be convened by DCG(I)

The committee could co-opt any other experts. The deliberation of the Committee should be coordinated by the office of DCG(I) and its report be made available in three months time after circulation of the minutes of DCC.

**Action – office of DCG (I)**

**AGENDA NO. 2**

**AMENDMENT OF RULE 66(1) OF NDPS RULES IN RESPECT OF DISPENSING OF MORE THAN 100 DOSES OF PSYCHOTROPIC SUBSTANCES TO THE PATIENTS IF RECOMMENDED BY RMP**

**The All India Organization of Chemists and Druggists have made a representation regarding the amendment of the proviso the Rule 66 (2) of the NDPS Rules which limits the quantity of possession of Psychotropic Substances for personal medical use to hundred dosage units. The AIOCD has represented that in long term treatment the psychiatrists prescribe Psychotropic Substances to be taken by a patient for long periods (4-6 months) and in such cases the chemists are required to dispense the drugs as per prescription of the Registered Medical Practitioner which would be in violation of Rule 66 (2) which restricts the maximum prescription quantity of 100 dosage units. The AIOCD has suggested incorporating a proviso to Rule 66 (1) as under:**

**"Provided further that an individual may possess quantity exceeding one hundred doses units at a time for his personal long term medical use if specifically prescribed by the Registered Medical Practitioner."**

**Under the Drugs and Cosmetics Rules there is no limit to the quantity, which can be prescribed by a Registered Medical Practitioner / possessed by an individual for his personal use. However Rule 65 (9) and 65 (10) states that substances specified in Schedule H and Schedule X to Registered Medical Practitioner, Hospitals, Dispensaries and Nursing Homes shall be made only against the signed order in writing which shall be preserved by the licensee for a period of two years.**

**Rule 65 (10) (c) further adds that the prescription shall indicate the total amount of medicine to be supplied and the dose to be taken. It would therefore mean that in specific case if more than hundred dosage units are required by a patient for his long term personal use the same can be dispensed by the pharmacist and can be kept by the patient for his personal use.**

**There are however restrictions on the import of drugs for personal use which restricts the quantity of drugs which may be imported for personal use. The quantity of any single drug is restricted to one hundred average doses.**

**DCC may deliberate the suggestion AIOCD so that the recommendation of DCC may be forwarded to the Dept. of Revenue, Ministry of Finance for their consideration.**

The matter was deliberated among the members of the committee. Majority of the members felt that there is a need to look into this issue in-depth, as there is a likelihood of misuse of this controlled drugs if large quantities are permitted to be stocked by an individual patient. It was also felt that this issue needs to be discussed by a select committee. Drugs Controller General (India) proposed that the matter could be referred to the Enforcement committee for through examination. In the mean time as the NDPS rules restricts 100 dosage units to be stocked by an individual the status quo should be continued.

**Action – Subcommittee on enforcement matter.**

## AGENDA NO. 3

**PROPOSAL FOR STRICT MENTIONING OF DIVERSION AND ABUSE OF NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES BY THE STATE DRUGS CONTROL AUTHORITIES**

**A concern has been expressed at various for a regarding the abuse potential and illicit trafficking of narcotic drugs and psychotropic substances viz. Codeine, Buprenorphine, Dextrapropoxyphen, Anxiolytic like Benzodiazepine etc. Off label use of many of these drugs in varying degrees has of course been reported world over.**
**The office of the DCG(I) has suggested preventive measures from time to time to curb the misuse of habit forming narcotic drug and Psychotropic Substances. Directives have been issued to All India Organization of Chemists and Druggists to involve Chemists and Druggists in India to disburse / distribute drug formulations containing narcotic drug and Psychotropic Substances with utmost caution and strictly adhere to the requirement of Drugs and Cosmetics Rules.**

**The requirements in respect of the manufacture for sale of for distribution or sell, stock exhibit or offer for sale, falls under Chapter IV of Drugs and Cosmetics Act, which is enforced by the State Government.**

**In view of the above, it is suggested that State Licensing Authorities may take steps to monitor the movement of narcotic drugs and Psychotropic Substances in their respective States specially wherever instances of possible abuse or movement of these from licit channel to illicit channel are evidence / or can take place.**

The DCG(I) briefed the committee regarding the concern expressed by the Members of the Parliament, the visual media and the press regarding diversion of Narcotic and Psychotropic substances to illicit use. The Human Right Commission had also taken a note through a PIL filed in the Commission. The DCG(I) also recalled his letter addressed to the Chemists Association with a copy to all the State Drug Controllers to sensitize their members regarding illicit diversion of these drugs. Recently the Narcotic Control Bureau has taken a proactive role under the NDPS Act to curb the illicit diversion of these drugs.

Since the requirements in respect of the manufacture for sale or for distribution or sell, stock exhibit or offer for sale falls under Chapter IV of Drugs and Cosmetics Act and Rules which enforced by the State Government, the DCG(I) instructed the State Drugs Controllers to take appropriate steps to check the illicit diversion of these drugs in the country.

**Action – All State Drugs Controller**

**AGENDA NO. 4**

**REGISTRATION OF TRADE MARKS FOR DRUGS IN INDIA BY THE NAME SIMILAR TO INTERNATIONAL NON-PROPRIETARY NAMES (INNS)**

**As you may be aware, the use of common stem in the Selection of International Non-Priority names (INNs) for pharmaceutical substances is approved by WHO. The same or similar stem once used in INNs for pharmaceutical substances approved by WHO is not to be used in Trade Marks (Brand Name) of pharmaceutical products. The WHO has brought to the notice of this Directorate of few instances of Registration of Trade Marks for pharmaceutical products of some manufacturers in India using similar stem as to that of INN approved by WHO. There is a list of common stems which have been selected by INN experts and are for use while selecting new International Non-Priority names for pharmaceutical substances that belong to an establish series of related compounds. For example the stem grel is used in INN Clopidogrel and thus if forms a part of the INN.**

**In view of the above, it is felt that the registration of Trade Mark with same or similar stem to that of INN needs to be prevented in India. The DCC members may deliberated the issue.**

The DCG(I) apprised the members that WHO has requested to take steps to prevent the registration of trademarks similar to International Non Preparatory Name(s) or having well established stem. This Directorate has been writing to the states as well as the registrar of trade marks for taking necessary steps in not registering trademarks similar to INN's or having well established stems. It has been decided to take up the issue with the all the professional Association like IDMA, OPPI, and Registrar of Trade Marks.

**Action – All State Drug Testing Authorities**

**AGENDA NO. 5**

**REPORT OF DCC SUBCOMMITTEE ON DUG TESTING LABORATORY**

**The Subcommittee has submi9tted its report on various issues including introduction of GLP under Drugs & Cosmetics Rules. A copy of the report alongwith the document prepared on the GLP requirements which may be incorporated as separate schedule is placed at Annexure – I.**

**Members may please examine the recommendations and deliberate in the meeting.**

The members complemented the efforts made by the Subcommittee. It was agreed that GCLP requirements may be incorporated as separate schedule. This would bring in uniformity in the understanding of basic principles of GLP by all those who are involved in drug testing work ranging from approved testing laboratories, inhouse laboratories of drug manufacturers, and the Government drug testing laboratories. Members were of the view that the principal of GLP and GMP should be given adequate focus in the B. Pharma. Course.

**Action – office of DCG(I). All State Drugs Controllers, All Govt. Analysts.**

**AGENDA NO. 6**

**SUBMISSION OF STATISTICAL INFORMATION PERTAINING TO PSYCHOTROPIC SUBSTANCES IN FORM P/BP TO NARCOTIC CONTROL BUREAU FOR ONWARD TRANSMISSION TO INTERNATIONAL NARCOTICS CONTROL BUREAU (INCB)**

**The office of Drugs Controller General (India) is required to send statistical information pertaining to the manufacture, consumption stocks, import & export of Narcotic drugs and Psychotropic substances to Narcotic Control Bureau for onward transmission to INCB. This information is to be obtained from the State Drugs Controllers. As the information was not forthcoming from the States, the matter was taken up in 34$^{th}$ DCC meeting and the State Licensing**

**Authorities had then agreed to furnish the information in Form P in respect of bulk drug only. In spite of an assurance given most of states are not sending even this information. The Ministry of Finance had taken a serious view and a high power mission on 5/5/2003 from INCB, Vienna held a meeting with senior officers of Ministry of Finance, NCB, New Delhi, CBN Gwalior and officers of Drugs Controller General (India). They stressed that statistical information w.r.t. Psychotropic Substances has to be furnished to INCB, Vienna under the International Treaties. The Union Secretary, Health had written to all State Health Secretaries / Administrations in this regard. Further on 21/10/2004, Director General, NCB had taken a meeting with State incomplete reporting in respect of statistics required buy INCB. The DDG, NCB apprised the participants that NCB is facing criticism for its inability to supply the required information and in absence of this information it is not possible to frame policies or modify existing regulations to control and monitor production and illicit diversion of Narcotic drugs & Psychotropic Substances.**

**With a view to discuss the above issued a meeting was convened by DCG (I) on 5/1/2005 with the State Drugs Controllers of Gujarat, Maharashtra, Rajasthan, M.P., Andhra Pradesh, Delhi, Assam, West Bengal, Karnataka, Punjab and officials from NCB, New Delhi. The purpose of this meeting was to identify gaps in data collection and the manner in which complete data as required by INCB can be collected and compiled in time and logistic problems faced by states in their inability to collect and furnish the information. The State Drugs Controllers expressed their inability to furnish the requisite information in Form P in respect of drugs formulations but agreed to furnish the information in respect of bulk drugs to this Directorate by 31$^{st}$ March so that the same could be compiled and sent to NCB before 30$^{th}$ of June every year. The minutes of this meeting were circulated to all the states. It is very disappointing that still the information has not been received from all the States.**
**DCC may deliberate in respect of the difficulties faced by the State Drugs Control Authorities and ensure that such international obligations are complied with utmost priority.**

This issue came up for discussion before the members of the committee. DCG (I) apprised the members that India is a signatory to the International Convention on Narcotic and Psychotropic Substances. As per the

requirement of the convention statistical information in Form P / BP and Form C are to be submitted to the Narcotic Control Bureau every year for onward transmission to INCB Vienna. It has been brought to the notice of the members time and again during the earlier DCC's that this information is not forthcoming from the states because of which India as to cut a sorry figure in International Forums. The Secretary Health has also written to all the Commissioners / Health Secretaries of the States to send this information well in time so that this information is not forthcoming from the states because of which India as to cut a sorry figure in International Forums. The Secretary Health has also written to all the Commissioners / Health Secretaries of the States to send this information well in time so that this International obligation could be fulfilled. The Drugs Controller General (India) had also taken a meeting with the selected drug controllers of the states the copy of the minutes of this meeting was circulated to all the states. In spite of these assurances in the past information from some of the states are still not forthcoming.

The Drugs Controller General (India) reiterated once again that this information should be sent annually by 31$^{st}$ of March, every year.

**Action – All State Drugs Controllers**

**AGENDA NO. 7**

**CONSIDERATION OF THE PROPOSAL OF REGISTRATION OF COSMETICS PRODUCTS FOR THE PURPOSE OF THEIR IMPORT INTO THE COUNTRY**

**AS the members of DCC are aware registration requirements for import of any drug into the country is in vogue by virtue of Notification No. GSR 604 (E) dated 24/8/2001, which came into force with effect from 01/04/2003. The Registration requirements are limited to the import of drugs into the country. However a need has been felt to have similar requirements in respect of import of Cosmetics into the country so as to ensure that their labeling and quality / safety profile is in conformity to the provisions under the Drugs and Cosmetics Rules.**

**Registration requirements for registration of cosmetics is not required to be as elaborate as it is for drugs.**

**It is proposed to provide for Registration of all Cosmetics to be imported in the country after screening the same and to charge a Registration fee of US$ 250 for each product including individual brand for the purpose. The modalities for incorporating the Registration requirements in the Drugs and Cosmetics Rules would be prepared accordingly.**

**The members of the DCC may give their considered opinion so that the Rules are framed and placed before DTAB for the amendment of the Drugs and Cosmetics Rules, 1945 for the purpose.**

The Members of DCC unanimously agreed to the proposal for introducing registration requirements in respect of all cosmetics. It was recommended that suitable provisions may be made in the Rule for this purpose prescribing a fee of 250 US dollars for each imported cosmetic product including individual brands. The Chairman informed the members that registration requirement for import of cosmetics does exist in few countries. This would enable proper monitoring of cosmetics being imported in large quantity from various counties. It was, however, agreed that unlike the registration requirements for drugs, the site registration may not be insisted in case of cosmetics.

**Action – Office of DCG(I)**

**AGENDA No. 8**

**CONSIDERATION OF THE QUESTION WHETHER ANIMAL FEED PREPARATIONS / FEED SUPPLEMENTS / FEED PREMIXES ARE TO BE CONSIDERED AS DRUGS UNDER THE PROVISIONS OF THE DRUGS & COSMETICS ACT AND COSMETICS ACT AND THE RULES THREUNDER**

**The 26th DCC (item No. 21) had considered the issue whether animal feed meant for veterinary use is to be considered as drug. The committee decided that ready mixed animal feed, containing Vitamins or other drugs in small proportions, may not be considered drugs. However, animal feed premixes containing drugs should be licensed under the Drugs & Cosmetics Rules.**

**Even though the above decision was taken in the 26th DCC animal feeds and the raw materials required for the manufacture of animal Feed / Premixes were continued to be imported without any import license under the provisions of the Drugs and Cosmetics Rules, 1945 although these products contained Schedule "C" and C (I) drugs.**

**To finalize this issue the 30th DCC set up Subcommittee to look into the entire gambit on the issues relating to Feed Premixes and Feed Supplements. The Subcommittee had submitted its report, which however was not discussed in the subsequent DCC. In the mean time this Directorate has been informed that the Hon'ble Supreme Court in the case of Sun Export Corporation Vs. Collector of Custom (1988) 111 STC 69 (S.C.) while considering whether "Feed Supplements" are "Animal Feed" has answered the question in positive i.e. feed supplements are animal feed. In the case the State of Gujarat Vs. Pfizer Limited the Hon'ble High Court of Gujarat had opined that though These products contains terrimycin, which is a drug, their primary and principal utility is that of treatment feed given to the poultry for increasing eggs productions by supplementary nutrition, they cannot be regarded as drug or medicine.**
**The matter is place before DCC for its consideration.**
Initiating the discussion DCG (I) pointed out that Animal Feed Grade Materials / Feed Premixes / Feed Supplements and Raw material used for the manufacture of such products containing vitamins and other drugs are being imported into the country and are also being manufactured in the country. Many of the State Licensing Authorities have not licensed the manufacturers of these products as a drugs under the provisions of the Drugs and Cosmetics Act and the Rules. These products are being manufactured and used for the maintenance and requirements for growth, and for fattening and for the purposes such as reproduction, for the production of milk, eggs, meat, wool etc. However, whether these products should be considered as a 'drug' and controlled under the provisions of the Drugs and Cosmetics Act and Rules, 1945 there under is not clear. Many of the raw material use in such products are drugs and the question which are arises at what stage these product are to be considered as drugs and not feed supplement is also not clear.

The matter was taken up with the Ministry of Agriculture for their comments in the matter pointing out that it has been brought to the notice of the Directorate that the Hon'ble Supreme Court in the case of M/s. Sun Export

Corporation Vs. Collector of Cuistoms (1998) has taken a view that the use of Vitamin, Antibiotics etc. in animal feeds and feed premixes in not be considered as drugs. The same view has been taken in the case of M/s. Glaxo Laboratoires India Pvt. Vs. Sate of Gujarat and State of Gujarat Vs. M/s. Pfizers Limited and up held by the Hon'ble Supreme Court.

The Ministry of Agriculture has informed that this is a crucial issue having wider implication as it may come with food chain as a residue. The matter is being examined by their department in consultation with experts and the views of their Ministry will be communicated to this Directorate.

Members agreed that this matter might be decided after receiving the views of the Ministry of the Agriculture.

**Action – Office of DCG(I), Department of AH & D**

**AGENDA NO. 9**

**PROPOSAL TO CONSIDER LABELING CORRECT NAME OF THE COLOUR USED IN DRUG FORMULATION ESPECIALLY CAPSULES AND TABLETES**

**It has been observed that many manufacturers are labeling their products especially in capsule forms stating 'Approved colours used in the empty capsules'. The State Licensing Authorities in the country are permitting such labeling considering that it complies with the requirements of the Drugs and Cosmetics Rules, 1945.**

**Drugs and Cosmetics Rules, 1945 under Rule 127 gives the list of colurs permitted to be used in drugs including both natural, artificial, coal tar colours and lakes. The same rule also provide that the label of the container of a drug containing a permitted colour shall indicate the common name of the colour.**

**In view of the above, DCC may deliberate and take a stand which may be followed uniformly by all State Drugs Control Authorities.**

Mentioning of correct name / names of color used in empty capsules on the label of formulations in capsules and tablets was discussed. The

manufacturers of empty capsules use different approved colors in combinations to get different colors combinations of the empty capsules. It is not possible for manufacture to mention the name of all the colors used in manufacturing of empty capsules. Many State Licensing Authorities in the country are permitting the manufacturer to mention on the label especially in capsules formulations stating. “Approved colors used in empty capsules.”

After discussion it was decided that if the label of capsules formulations is bearing “approved colours are used in the capsules” may be adequate to comply with the provisions of the Drugs and Cosmetics Rules and such products should not be termed misbranded and to bring uniformity all the members agreed to follow the above practice.

Action – All State Drugs Controllers

**AGENDA NO. 10**

**PROPOSAL TO AMEND RULE 49 AND 49 A OF THE DRUGS AND COSMETICS RULES, 1945 REGARDING QUALIFICATION OF THE INSPECTORS AND LICENSING AUTHORITIES TO INCLUDE BACHELOR OF VETERINARY SCIENCES WITH SPECIALIZATION IN VETERINARY PHARMACOLOGY OR VETERINARY MICROBIOLOGY OR VETERINARY MEDICINE AS QUALIFICATION**

**The agriculture Production Commissioner U.P. has written to the Govt. of India that under Rule 49 pertaining to the qualifications of inspectors and Rule 49 A pertaining to qualification of a licensing authority, the veterinary qualification has not been included. The present Rule states that a person who is appointed under the above Rules shall have a degree in Pahrmacy or Pharmaceutical Sciences or Medicine with specialization in clinical pharmacology or Microbiology from a university established in India by law. These Rules do not include qualification of veterinary sciences. It has been requested that the above Rules should be amended so that the prescribed qualification should also include Bachelor in Veterinary Sciences with specialization in Veterinary Pharmacology or in Veterinary Microbiology or in Veterinary Medicine.**

**DCC may deliberate the suggestion and give its opinion in the matter.**

The Chairman informed that in order to check the misuse of Oxytocin injection Agriculture commissioner, UP has proposed that rule 49 & 49 A of Drug and Cosmetics Rules be amended to incorporated to incorporate Bachelor of veterinary Science with specialization in Veterinary Pharmacology or Veterinary Microbiology or Veterinary Medicines. Chairman informed that in the past, issues regarding misuse of Ocytocin inj. In Veterinary Practice had been discussed at various for a considering the use of Oxytocin inj. in the medical and Veterinary Practices and since Oxytocin inj. figures in the list of essential medicines, it was not advisable to ban the drugs. However, its sale was regulated by amending Pack size of Oxytocin inje. In single blister pack against the earlier prescribed large packing containing 50-100 ampoules and all the State Licensing Authorities have been advised that sale of oxytcoin inj should be made through retail out lets for veterinary use, strictly against the prescription of Regd. Veterinary Practitioners.

While on discussion, it also emerged that Veterinary Science is a separate discipline and is mainly concerned for Animal Health. In so far qualify of Veterinary Drugs is concerned, the present rule under D & C Rules, is sufficient to monitor the quality, safety, efficacy moving in the market, by the State Drugs Controller through their Drugs Inspectors Opinion from Veterinary experts is taken whenever so required.

The member also apprised to the Chairman that as and when any misuse of veterinary drugs, including Oxytocin injection is reported in their State adequate procedure is followed as per D & C Rules. After the discussion, it was decided that at present there is no requirement for amending the rule 49 and 49-A, under D & C Rules so as to include B.V.Sc aas an additional qualification for Licensing Authority. The specific problem cannot be contained by merely notifying Veterinary graduate on licensing / enforcing authority. However, chairman requested Drugs Controller, UP to check the reported misuse of Oxytocin injection in their State and taken suitable action.

**Action – Drugs Controller U.P.**

**AGENDA NO. 11**

**CONSIDERATION OF THE QUESTION WHETHER ANIMAL FEED PREPARATION / FEED SUPPLEMENTS / FEED PREMIXES ARE TO BE CONSIDERED AS "DRUGS" UNDER THE PROVISIONS OF THE DRUGS AND COSMETICS ACT AND THE RULES THEREUNDER**

**As the members are aware that animal feed grade materials / feed premixes / feed supplements / poultry fee supplements etc. and the raw material used for the manufacture of such products are being imported into the country since decades. The products are used for the maintenance and requirements for growth, and fattening and for purposes such as reproduction, for production of milk, eggs, meat, wool or feathers and for efficient output of work etc. However, the issues whether such feed supplements, premixes etc should be considered as 'drug' and to be controlled under the provisions of Drugs and Cosmetics Act and the Rules there under is not clear. Many of the raw materials which to into the manufacture of feed supplements and feed premixes could also be used as 'drugs' and the question arises at what stage these products are to be considered as drugs and not feed supplements. Schedule D of the Drugs & Cosmetics Rules gives exemption for import of substances not intended for medicinal purposes from the provisions of Chapter III of the Drugs and Cosmetics Rules and hence no Registration and import License required for the import of these substances not intended for medicinal purposes subject to the condition stated herein. This Directorate had also sought the opinion of Ministry of Agriculture, Department of Animal Husbandry on this issue. However no final reply has been received.**

**It has also been brought to the notice of this Directorate that the Hon'ble Supreme Court in the case of M/s. Sun Export Corporation Vs. Collector of Customs (1998) has taken a view that the use of Vitamin, Antibiotics etc in animal feeds and feed premixes is not be considered as drugs.**

**The matter is placed before DCC for their consideration.**

The matter has already been discussed vide agenda No. 8.

**AGENDA NO. 12**

**PRESENCE OF ALLOPATHIC DRUGS SUCH AS SILDANEFIL CITRATE IN AYURVEDIC PRODUCTS**

**Instances have come to notice of this Directorate that allopathic drug such as Sildenafil citrate is added in Ayurvedic preparations. For example a sample of Titanic-K2-Capsules manufactured by M/s. Sun Labs Pvt. Ltd, Oral, UP was drawn by Central Drug Inspector, East Zone, Kolkata and was sent to Government Analyst, CDL, Kolkata. It was found to contain Sildanefil Citrate, which is an allopathic ingredient.**

**Therefore, the preparations, which is manufactured, as an Ayurvedic product is not only adulterated and misbranded but also, manufactured without a valid license and contravenes Sec 18(c). The matter may be discussed in DCC so as to control the addition of allopathic drugs to Ayurvedic preparations.**

The Chairman drew the attention of all members about instance of Ayurvedic preparation found to be adulterated with Sildnafil Citrate an allopathic drug to treat erectile dysfunction. This brings a bad name to Ayurved and shakes the confidence of consumers. It is a heinous crime.

Members expressed very serious concern on the movement of such Ayurvedic preparations containing allopathic drugs, which are to be considered as spurious, misbranded, adulterated, manufactured without drug licence. All the members felt the Drugs Control Authorities in the country should remain vigilant to tackle the problem and samples of Ayurvedic drugs suspected to contain allopathic medicines should be drawn regularly and sent for testing for presence of any allopathic medicines. Defaulting firms or the culprits involved should be identified and prosecuted and strict action should be taken against them.

The instances should also be immediately brought to the notice of authorities dealing with ISM drugs.

**Action – State Drugs Controller including those regulating Ayurvedic drugs.**

**AGENDA NO. 13**

**DOCUMENTS TO ACCOMPANY WITH THE LICENSE FOR THE GRANT / RENEWAL SENT FOR APPROVAL OF CLAA TO MANUFACTURE LVPS**

**The large volume parenterals are sensitive products and therefore approving the grant of license / renewal of the license / permission for the manufacture of additional products requires detail information on facilities for manufacturing and testing.**

**It has been observed that the license for the grant and renewal of certificates are sent to CLAA without supporting documents such as 1. Verified and approved plan of manufacturing premises 2. List of equipments and machinery 3. Qualifications and experience of the technical staff responsible for manufacturing and testing 4. Detailed facilities provided for quality control department along with the list of equipments, reference books etc.**

**In the absence of the information / background about the facilities provided by the firm, it is difficult to take the decision.**

The large volume parenterals, vaccines, blood products, and recombinant products are sensitive products. Grant / renewal of the license and permission for the manufacture of these products are to be duly approved by the CLAA. This requires that at the level of SLA, it should be ensured that all documents are in order and are sent to CLAA.

All the members agreed to send following documents to CLAA for approval of grant of license on Form 28D and renewal on Form 26 H to manufacture LVPs:-

1. Site master file
2. Verified and approved plan of manufacturing premises
3. List of equipments and machinery
4. Qualifications and experience of the technical staff responsible for manufacturing and testing of the drugs.
5. Details of facilities provided for quality control department along with the list of equipments and reference books etc.
6. Copy of the joint inspection report and verification of compliance with full details of observations on all critical steps followed by the firm and manufacturing of LVPs.

7. Details of samples found to be not of standard quality, if any, manufactured by the concerned firm, in case of renwal of the licence.

**Action – Similar action to be taken in case of other CLAA items, All State DC**

**AGENDA NO. 14**

**MANUFACTURE AND SALE OF DISINFECTANTS SUCH AS HARPIC, KIWIKLEEN, SANIFRESH ETC**

**It has been brought to the notice of the Health Secretary, Min. of HFW that the manufacturers are manufacturing disinfectants such as Harpic, Kiwi-Kleen and Sanifresh etc. without a valid drug license as required under Sce 3(b) (ii) of the Drugs and Cosmetics Act and thus violating Sec 18(c) of the Act.**

**As per there is no clarity for not allowing the requirements of the provisions of Drugs and Cosmetics Rules 1945 about the manufacturing of above category of disinfectant.**

**The matter requires to be discussed in length for the implementation of the provisions of Part II of the Schedule O, and to bring the manufacturers of these disinfectants under valid license.**

DCG(I) briefed the members that disinfectant fluids fall under sub clause (ii) of clause (b) of section 3 of the Drugs and Cosmetics Act. The Government of India vide Gazette notification No. 1-20/60-D dated 2/6/1961 specified that the disinfectant fluid made from synthetic or naturally occurring substances other than those derived from colta oils etc., by virtue of their compositions possessing disinfectant prosperities or with claim to possess disinfectant properties would be considered as drugs.

In view of the above disinfectant fluids falling under the above definition would be considered as drugs. The State Drug Control may take steps accordingly so that these are manufactured under a proper licence under the Drugs and Cosmetics Rules.

**Action – All State DC's**

**AGENDA NO. 15**

**MEDICAL DEVICE REGULATION**

**As the members are aware, currently there is no separate regulation to control manufacture and marketing of medical devices in the country. However, a scope has been provided vide Section 3 (b) (iv) of Drugs and Cosmetics Act and the Central Government to regulate such medical devices as it may be appropriate to notify from time to time.**

**The following medical devices have so far been notified:-**

- **Sterile disposable perfusion sets for single use only.**
- **Sterile disposable hypodermic syringes for single use only.**
- **Sterile disposable hypodermic needles only.**
- **In vitro diagnostic devices for HIV, HBsAg and HCV.**

**There is an increasing concern to regulate medical devices which also found an important component of healthcare products. The Mashelkar Committee makes the following recommendations:**

a. **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;**
b. **A specific Medical Devices Division should be set up in the office of newly structured CDA for proper management of approval, certification and quality of medical devices; and**
c. **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.**

**The matter is under examination of the expert committee to suggest appropriate amendment in the Act and Rules. Recently, the report of the committee constituted by the office of the Principal Scientific Advisor to the Government of India on "Scientific Evaluation and Sterilization Practices in India" expressed concern about the status of sterility in various medical devices marketed in the country in sterile form. The committee also recommended that surgical gauze and cotton should be sold after sterilization with gamma radiation as**

**on other form of sterilization is acceptable for these items under Indian circumstances.**

**Till such time, a separate definition of medical devices is brought in to regulate them, it is considered appropriate to notify all "sterile medical devices" under Section 3 (b) (iv) of Drugs and Cosmetics Act.**

**The members of DCC may deliberate the issue and give their suggestions.**

The issue of regulatory control over medical devices, which is an important category of health care products, was deliberated in detail by the Committee. It was felt that presently there is a vacuum in the country in respect of regulation over import, manufacture and sale of most of medical devices. In most of the development countries the respective drug regulatory agencies are performing such function and have created separate capacities in terms of trained manpower for evaluation of wide range of medical devices. It was felt that amending the Act to introduce a separate definition for medical devices may take suitable time. The committee constituted for this purpose has yet to submit his report.

However, lawmakers did provide powers to Central Government to bring medical devices under regulatory ambit as and when so desired by notifying such devices under Section 3(b) (iv) of the Act. DCC also agreed with the concerned expressed by the Committee constituted by the office of Principle Scientific Adviser to the Government of India expressing an urgent need to provide adequate regulatory mechanism on medical devices.

The Committee unanimously agreed to the proposal to cover large number of critical medical devices by notifying that as a class i.e. "sterile medical devices" under Section 3(b) (iv) of the Act. It was, however, opined that government should take immediate steps to provide necessary wherewithal in terms of manpower and net-working capacity with subject experts in CDSCO to enable it to handle the expected additional workload in an efficient and professional manner. The Committee observed that some Indian enterprises have started manufacturing sophisticated devices like DES, hear valve etc. A mechanism needs to be in place to officially

approve these products. The would help in better acceptance of their products by the stakeholders.

**Action – Office of DCG(I)**

**AGENDA NO. 16**

**GRANT OF FRESH LICENSES DUE TO CHANGE IN CONSTITUTIONS / NON RENEWAL IN TIME EITHER BY STATE LICENSING AUTHORITY / LICENSEE**

**It has been observed of late that there has been a steep increase in the grant of fresh license to existing Blood Banks either due to change in constitution or due to the fact that the licenses were not renewed in time either by the State Licensing Authority or the licensee. Further, the regularization of period from the expiry of license to the grant of license is not known in many such cases.**

**Also, a regular monitoring of Private Commercial Blood Banks in the state should be taken up by State Licensing Authorities as a number of instances of bleeding or professional donors, transfusion of untested blood & similar such cases are often being highlighted in the print and visual media.**

**This matter may be discussed in the DCC and State Licensing Authorities may be advised to avoid such instances as far as possible.**

After discussion, Chairman requested all the States to renew the licence of Blood Banks, well in time and no Blood Banks shall function without a valid license. All private Blood Banks shall be inspected at regular interval to check the possible malpractices like collection of blood from professional paid donors and also issue of blood without complete testing. Members were advised to send a list of Blood Bank licence which are pending for more than one year for renewal.

**Action – All State Drug Controller / All Zonal / sub zonal officers.**

## 5. STATE AGENDA ITEMS

## RAJASTHAN

**AGENDA NO. 17**

1. **Deletion of the definition for "Poisonous Substances":**
   **Since Schedule – E has been omitted vide GSR 462 (E) dated 22/06/82 therefore, definition for poisonous substance under Rule 2 (j) should also be omitted.**
   DCG(I) briefed the members that Poisonous Substances are now controlled by the Ministry of Home Affairs and the list of the Poisonous Substances under Schedule E of the Drugs and Cosmetics Rules was omitted vide GSR 462 (E) dated 22.06.1982. However, the definition of Poisonous Substances under Rule 2(j) refers to Schedule E and it was proposed to delete the above definition.

   Members agreed to the proposal for deletion of sub rule (j) of Rule 2 of the said rules.

   **Action – Office of DCG(I).**

2. **Prohibition from advertising prescription drugs (Sch. H & Sch. X) in news papers, electronic media etc.**

   **Sch. 'H' & Sch. 'X' drugs are required to be made available to the patients on the written prescription of Registered Medical Practitioners as per the provisions of the Drugs & Cosmetics Act and Rules thereunder. Hence such drugs should not be permitted to be advertised in magazines, newspaper, TV or though electronic media for which suitable amendment in Rules under the Drugs and Cosmetics Act on in Drugs and Magic Remedies (Objectionable advertisement) Act may be incorporated.**

   The proposal pertained to prohibiting the advertisements of drugs covered under Schedule H and X (i.e. prescription drugs), through pres or electronic media. DCG(I) informed the members that Drugs and Magic Remedies (Objectionable advertisement) Act, 1954 is proposed to be amended so as to provide prohibition of advertisements of drugs belonging to Schedule H and X. He further informed the committee that it is also proposed to enhance penalties for offence under the

Act. A Bill to amend the said Act would be placed before the Parliament by Ministry of Health.

**Action – Office of DCG(I).**

3. **Schedule 'G' drugs: To be incorporated as prescription drugs:**

**Schedule 'G' drugs are required to be taken under medical supervision as per the caution under Rule 97 of Drugs and Cosmetics Rule 1945 whereas Sch. 'H' & Sch. 'X' drugs are required to be sold by retail on the prescription of RMP's only and are not required to be taken under their supervision.**

**Thus by reading caution under Rule 97(a) for Sch. 'G' drugs and warning for Sch. 'H' & Sch. 'X' drugs under Rule 97 (b) and 97 (d), it appears that the warning of Sch. 'G' drugs goes beyond the scope of sale along, to the extent of administration and use under medical supervision. It is surprising that sale of Sch. 'G' drugs is not governed under prescription of a Registered Medical Practitioner. It is therefore proposed that beside caution the warning of Sch. 'H' & Sch. 'X' drugs should also be made mandatory under Rule 97 for Sch. 'G' drugs.**

Schedule 'G' drugs are required to be taken under medical supervision as per caution under Rule 97 of Drugs and Cosmetics Rules, 1945, where as Schedule 'H' and Schdule 'X' drugs are required to be sold by retail on prescription of 'RMP's only and not necessarily required to be taken under their supervision.

Thus it appears that sale of Schedule 'G' drugs is not governed under prescription of Registered Medical Practitioners.

The Chairman informed that Schedule 'G' requires to be taken under medical supervision, as not most of these drugs are either anti-cancer or critical care drugs. Some of these Schedule 'G' drugs are, however, also listed under Schedule 'H'.

*The DCC members agreed upon the view points of the Chairman and suggested that a similar proviso may be inserted under Rule 97(1) (a) which reads as follows:*

"Schedule 'G' Drug – Warning: To be sold by retail on the prescription of a Registered Medical Practitioner only".

**Action – Office of DCG(I).**

4. **Directions regarding specific usage of New Drug Formulations: Provision to be incorporated in Rule 97:**

**New drugs like Mifepristone, Sidelnafil Citrate, Tadalafil and Ateepher are required to be sold under Specific labeling directions as per the conditions imposed by DCG(I) at the time of their approval but there is no corresponding rules for doing so under Drugs and Cosmetics Rules and therefore provision to incorporate such specific conditions and sale under prescription of RMP should be incorporated.**

Members agreed to the proposal and authorized the Chairman to examine feasibility of suitably amending relevant provisions under the rules.

**Action – Office of DCG(I).**

5. **Extending the testing facilities of approved institutions to purchasers and consumers too"**

**The approved institutions on Form 37 can analyze samples of raw materials, Drugs and Cosmetics, which are sent to them by the licensed manufacturers and report of analysis is to be released on Form 39. However, such institutions can not legally accept samples from purchasers and consumers for analysis as per the existing provision. This issue is stated to have been discussed earlier in DCC meeting and it was decided that there seems to be no need to bring out any change in the Rules. However, now it is felt that there is a strong need to bring out changes in rules so that the test reports issued by approved institutions for samples sent to them by various government and private purchasers / tendering institutions and consumers have legal sanctity.**

DCG(I) explained that the proposal is to provide legal sanctity to the reports issued by the approved testing laboratories for testing samples sent to them by various government and private purchasers / tendering institutions and consumers. At present these laboratories test samples on behalf of licensees for manufacture of drugs or cosmetics. It would be desirable in the present circumstances to involve these laboratories in testing of drug samples from public to release pressure from government laboratories. However, the matter require

further consideration as the performance of laboratories varies from State to State and where reports issued by such laboratories approved in one State would be acceptable in the other State also. Drugs Controller, Rajasthan may give detailed proposal for further examination.

**Action – Drugs Controller, Rajasthan.**

6. **Defining "Normal room temperature" under Schedule 'P':**

**Schedule 'P' of Drugs and Cosmetics Rules specifies life period of drugs and conditions of their storage. The 'Note' in the end of Sch. 'P' defines Cool & Cold place for storage as required under column 4 of the Schedule but the term "Normal room temperature:" is not defined. AS the Normal room temperature throughout the country may varies from 0°C to 45 °C, therefore it will be appropriate if the term "Normal room temperature" is also defined like cool & cold place.**

The matter was discussed at length. The note at the end of Schedule 'P' under Drugs and Cosmetics Rules does not define the term "Normal Room Temperature". However, Indian Pharmacopoeia 1996 under General Notices defines the term 'Room Temperature' as "The temperature prevailing in a working area" the Committee therefore decided to refer the matter to the Indian Pharmacopoeia Commission for seeking its views.

**Action – Indian Pharmacopoeia Commission.**

7. **Constitution of the manufacturers and dealers are not made available by some State Drugs Controller for institution prosecutions against defaulters who are responsible for manufacture and sale of grossly sub standard drugs:**

**It has been observed that many a times the constitutions to file court cases under the Drugs and Cosmetics Act for manufacturing and selling grossly substandard drugs are not made available by some State Drugs Controllers and therefore the institution of cases in the courts are delayed or even the cases are time-barred. The Legislative Assembly, investigating Agencies, Human Rights Commission, Lokayukta etc. views this as major negligence and at times have taken vary serious note on such issues. It is therefore proposed that unanimous decision should be taken by the DCC that as and**

**such information are sought by any State Drugs Controller, it should be made available without delay.**

This issue, as was recalled by many members, has been discussed number of times in the meeting of DCC.

The committee took a serious view of it and requested all the State Drugs Controllers to provide the information without delay as and when so required.

**Action – all Drugs Controller's.**

## MIZORAM

**AGENDA NO. 18**

1. **Ban of formulations containing Dextropropoxyphene Hcl with Paracetmol drug to its fatal side effect and its highly abusive property.**
2. **Disbursement of Plan Fund earmarked for North Eastern States Drugs Control Administration as allocated in the financial year, 2003-2004 Budget or any clarification thereof.**

The issue was deliberated in the meeting. Dextropropxyphene in 135 mg per dosages unit or 2.5% in undivided preparation provided that such preparations do not contain any substances controlled under the convention of Psychotropic Substances 1971 convention, such a substance do not fall within the definition of a manufactured drug. This combination has therapeutic use. It acts on central nervous system to produce analgesia. This combination continues to be used for treatment of various types of pain like headache, toothache, Myalgia and pain in other parts of the body. It was decided that inspite of its misuse potential of Dextropropoxyphene this drug combination have therapeutic use and cannot be banned.

## ORISSA

**AGENDA NO. 19**

**Maximum quantities with categories of drugs to be kept by Registered Medical Practitioner under the provision of Sch. 'K' read with Rule 123 of Drugs & Cosmetics Rules 1945 for treatment of his own patients.**

The matter was discussed by the Sub Committee on Enforcement matters and said committee opined that a limit of maximum Rs. 10,000/- in terms of value may be prescribed as limit of stocks by the R<Ps and the same may be stipulated as one of the conditions under Schedule K.
DCC accepted the views of the Sub-committee.

**AGENDA NO 20**

**AMENDMENT OF RULE 55-A OF DRUGS AND COSMETICS ACT**

**In accordance with the provisions of the above rule, Drugs Inspectors shall return the documents seized by him under clause (c c) or produce before him under clause (c c a) of sub section (1) of section 22 of the Act within a period of twenty days from the date of such seizure or production to the person from whom seized or produced after keeping certified copies signed by the Drugs Inspector and person concerned.**

**In the above rule, the following ambiguities and difficulties are experienced.**

**(i) Drugs Inspector, after seizure of the documents has to inform judicial Magistrate and take his order as to the custody thereof under section 23(6) of Drugs & Cosmetics Act. Hence the seized documents become the property of the court and without order of the Judicial Magistrate, those documents cannot be parted.**

**(ii) No court will take cognizance of an offence on the certified copies, since for taking cognizance of an offence original document is essential as per the Evidence act.**

**In view of the above, necessary amendment may be made in Rule 55-A to provide copies of the documents duly certified by Drugs Inspector to the person from whom seize who produce the same under section 22(1) c c and 22(1) c c a of Drugs and Cosmetics Act 1940 instead of original documents.**

This matte was referred to the Sub-Committee on legal issue and sub-committee opined that no amendment is necessary in respect of Section 22 (A) of the Drugs and Cosmetics Act but necessary amendment may be made in Rule 55-A so that certified copy of such seized document can be accepted in the court of law as primary evidence.

After a detailed discussion in this matter the DCC accepted the view of Legal Sub-committee in this regard.

**AGENDA NO. 21**

**AMENDMENT OF RULE 2 (DD)- DEFINITION OF HOMEOPATHIC MEDICINES**

**In accordance to the above rule, the definition of Homeopathic medicines is as under:-**

**In the last two lines "But does not include a medicine which administered by parenteral route. The meaning of parenteral route means administrered, elsewhere than in the alimentary canal as per "Oxford Dictionary".**

**From the above it is evident that the Homeopathic medicines only is to be administered by oral route by mouth. At present different type of dosages from homeopathic medicines like Ophthalmic preparations (eye drops), ointments etc., are being manufactured for sale of these drugs are being administered by other routes like administered on eyes of skin etc.**

**In view of the above the work 'Parenteral' may be substituted with injectables.**

The committee is of the opinion that the matter may be referred to Homeopathic sub-committee for examining the issues in details.

However, except for injectable, other doses form of homeopathic drugs have been in use for considerable period.

**Action – Office of DCG(I) / Homeopathic Sub-committee.**

**AGENDA NO. 22**

**AMENDMENT OF SCH. 'K' READ WITH RULE 123 PARA 5 AND 5 A**

**No Govt. Hospitals / Private Hospitals / Nursing Homes keeping drugs for consumption of their own patients or distribute the same to other hospitals shall not distribute the drugs after expiry date.**

DCG(I) briefed the members that similar proposal was placed before DCC by the Drugs Controller, Kerala in its 35th meeting, and the proposal was referred to the subcommittee on enforcement matters. The committee has recommended that entry under 5 and 5-A of Schedule K should be amended to include a condition that provisions of clause (17) of Rule 65 shall also be complied with.

The members agreed to the recommendations of the subcommittee and recommended that entry 5 and 5-A should be suitable amended so that date expiry drugs are not dispensed by the RMP's or hospitals / dispensaries to their patients.

**Action – Office of DCG(I)**

**AGENDA NO. 23**

**Section 22(1) (d) empowers an inspector to exercise such other powers as may be necessary.**

**Specific provision may be made under section 22 to empower the Inspector to lock and seal any premises where he has reasons to believe that any offence under Drugs and Cosmetics Act 1940 is being committed or about to be committed.**

**In case of suspension of licenses or non availability of any person incharge in any licensed or unilicensed sales or manufacturing premises, the above lock and seal procedure could be enforce as per the provisions laid down under Cr. P. C.**

The committee is of the opinion that in specific case, the concerned Drugs Inspector may use the power conferred to him under Section 22 (d) which is adequate. However, in such case, the concerned Controlling Authority should immediately be informed. No amendment is considered necessary in respect of section 22 of the Drugs and Cosmetics Act.

**AGENDA NO. 24**

**Section 22 empowers the Inspector to issue orders in Form 15 asking the person in possession of the drugs, cosmetics not to dispose off the same for a period not exceeding twenty days.**

**It is normally not possible to complete investigation within twenty days; the period may be increased to thirty days.**

The committee agreed with the opinion of legal subcommittee (item No. 21) that the period of 20 days may be enhanced to 30 days. But amendment of Drugs and Cosmetics Act is necessary to do so which may take long time. In the mean time, in specific case, the concerned Drugs Inspector may use the power conferred to him under Section 22 (d) for any difficulties arising out from section 22(c). However, in such case, the Conferred Controlling Authority should be informed.

**Action – All State Drugs Controller**

**AGENDA NO. 25**

**RULE 122 B MAY BE SUITABLY AMENDED AS**

**"Application for approval to manufacture new drug" instead of application for approval to manufacture new drug other than the drugs classifiable under schedules C and C 1 as Rule 122-C is omitted vide GSR No. 900 (E) dated 12/12/2001.**

In notification GSR No. 900 (E) dated 12/12/2001, the rule 122 C has been omitted which was related to drugs under C & C1, but heading of the Rule 122 B reads as "Application for approval for manufacture new drugs other than drug classified under Schedule C and C1" which is contradictory. Therefore, the heading of the Rule 122 B may be amended as "Application for approval to manufacture New Drug".

The Chairman informed to the members that heading of the Rule 122 B needs correction. Members agreed for said correction, as "Application for approval to manufacture New Drug".

**Action – Office of DCG(I)**

## GOA

**AGENDA NO. 26**

**CONSIDERATION OF THE QUESTION OF RECOGNIZE RESEARCH AND DEVELOPMENT LABORATORIES, UNDER THE PROVISIONS OF THE DRUGS AND COSMETICS RULES, 1945**

**There is no provision laid down under the Drugs and Cosmetics Rules, 1945, to recognize / license the Research and Development Laboratories. Of late, it is seen that some of the manufacturers have started setting up so called Research & Development Laboratories, which in real sense are not Research & Development Laboratories, but are Formulation development laboratories and they transfer / sell the technology to other units. Clarification is sough (i) whether license in Form – 29 can be granted to such laboratories and what will be their liability; (ii) If loan license unit sets up such independent facility then now to tackle such issues. Guidelines / provision under the law be provided for such issues.**

**After a detailed discussion the members unanimously decided that the issue requires an in depth examination and may be referred to such committee on enforcement matters.**

**Action – Subcommittee on Enforcement matter.**

**AGENDA NO. 27**

**CONSIDERATION OF THE QUESTION TO MAKE PROVISIONS FOR DRAWING OF SAMPLES FROM THE SALES PREMISES UNDER RULE 51, I.E. DUTIES OF INSPECTORS OF PREMISES LICENSED FOR SALE**

**It is noted that there is no provision under Rule 51 to draw the samples from the sales outlets except to draw the samples from imported packages, as specified under Sub-Rule 3 of Rule 51. Therefore, there is a need to amend the said rule suitably.**

**The matter was discussed in detail and the committee was of the opinion that in specific case the concerned Drugs Inspector may use the power conferred to him under section 20(d) and draw the samples from the sales outlets. Hence there is no need to amend the present rule.**

**AGENDA NO. 28**

**CONSIDERATION OF THE QUESTION TO MANUFACTURE DRUGS WHICH ARE HAVING OVERLAPPING INDICATIONS, I.E. CYTO-TOXIC / IMMUNE SUPPRESSANT DRUGS**

**As required under Schedule M of the Drugs and Cosmetics Rules, 1945 there shall be separate facility for manufacture of Cytotoxic drugs. However, it is seen that drugs like Cyclosporine, which are having immune-suppressant properties, are also manufactured in the same section, wherein Cytotoxic drugs are manufactured.**

**In view of the above, suitable clarifications / guidelines may please be issued whether immune-suppressants can also be manufactured in the same area where Cytotoxic drugs are manufactured, or they should be manufactured in the general section, or separate area should be provided.**

The committee observed that as a precautionary measures against mix-up and cross contaimination under Part-I, Para No. 8.2.2 or Schedule 'M', it has been prescribed that processing of sensitive drugs like B. Lactuns antibiotics, sex hormones and cytotoxic substances should be made in segargated or isolated production area within the building with independent AHU & proper pressure differentials.

For cyclosporine, which is having immune-suppressant properties, the same logic is applicable.

The committee is of the opinion that if the licensee ensure proper cleaning validation, the S.L.A. may allow the production of cyclosporine drugs in the same section, wherein cytotoxic drugs are manufactured, on campaign change basis.

**Action – All State DC's**

**AGENDA NO. 29**

**CONSIDERATION OF THE QUESTION TO SPECIFY ACTUAL TIME AND QUANTITY, BY THE GOVERNMENT ANALYST ON FORM – 13**

**It is noted that as and when any product fails in respect of Disintegration Test or Dissolution Test, or some other critical tests like uniformity of contents, etc., actual values are not recorded in the test report issued on Form 13, thereby it becomes difficult for the Investigating Officer to appreciate the degree of seriousness of defect. It is, therefore requested, that in case any product fails with respect to the above, then the observed values of time, percentage, etc., with respect to such tests, should also be recorded in Form 13, which will help in investigating.**

The committee examined the issue in detail and is of the opinion that the time taken for disintegration or dissolution should be recorded in the test report in Form – 13 issued by the Govt. Analyst. It was also decided to conduct a survey for S.R. Products regarding dissolution profile. Such survey would be conducted by the West Zone office of CDSCO.

**Action – All Govt. Analysts, DDC(I) West Zone, officer of CDSCO.**

**AGENDA NO. 30**

**CONSIDERATION OF THE QUESTION WHETHER SWEETENING AGENT LIKE NEOTAME, CAN BE PERMITTED IN THE MANUFACTURE OF ORAL REHYDRATION SALTS (ORS), AS WELL AS WHETHER CITRIC ACID CAN BE ADDED TO INCREASE THE PALATABILITY OF THE PREPARATION**

**The revised monograph of ORS prescribes specific quantities of ingredients to be added in ORS preparations, so also it describes the osmolarity of Sodium, Calcium and Citrate, as well as the total osmolarity. Sodium Citrate is one of the active ingredient in the ORS formulation. It is noted that some manufacturers are adding, additional**

**quantity of Citric Acid, as taste enhancer in the formulation which may increase osmolarity of Citrate Ions.**

**Further, monograph permits additional of Aspartam and Sodium Saccharin in a limited quantity as a sweetening agent, in ORS. Of late, some of the manufacturers are seeking permission to add Neotame as sweetening agent in ORS, based on the clearance given by the Drugs Controller General (India) as sweetening agent.**

**The above may please be deliberated with respect to addition of Citric Acid and Neotame in ORS formulations.**

The monograph of ORS prescribed specific quantities of ingredients to be added in ORS formulation, so also it describes the osmolarity of Sodium, Calcium and Citrate, as well as the total Osmolarity. It is observed that some drug manufacturers are adding additional quantity of Citric Acid, as taste enhance in ORS formulations, which may increase the osmolarity of Citrate ions. Of late some of the manufacturers are seeking permission to add NEOTAME as sweetening agent in ORS.

This issue was deliberated and members suggested that after further examination / evaluation by office of DCG(I) appropriate decision may be taken and conveyed to all members.

**Action – Office of DCG(I).**

**AGENDA NO. 31**

**CONSIDERATION OF THE QUESTION WHETHER PRODUCTS MANUFACTURED IN ONE STATE CAN BE PERMITTED TO BE PACKED IN ANOTHER STATE**

**Number of requests have been received in the State, requesting for permission to manufacture tablets / capsules in bulk quantity to be transferred to other States for packing. It appears that the reason for such application is exemption from payment of Excise duty granted in other States. Such products may be shown to be manufactured in that State, which may result in evasion of Excise duty. It is requested to deliberate on the issue for the sake of uniformity to be followed in the country.**

The committee is of the opinion that no such permission should be granted as general rule. However in specific cases and after recording the records the State Licensing Authority may consider the request & permission may be accorded and endorsed in the manufacturing license. However, the enforcement subcommittee should examine this issue.

**Action – All State Drug Controller.**

**AGENDA NO. 32**

**CONSIDERATION OF THE QUESTION WHETHER MANUFACTURE OF COSMETICS CAN BE PERMITTED IN THE SAME AREA WHEREIN THE DRUGS MEANT FOR EXTERNAL USE ARE PERMITTED**

**It has been brought to the notice that certain States are granting permission to manufacture cosmetics in the same area, where the drugs for external use are manufactured. The above may please be deliberated whether in the same areas license for cosmetics on Form – 32 can be issued wherein manufacturing license on Form 25 and Form 28 have already been issued and vice-versa.**

The matter was discussed at length. The Committee is of the opinion that in specific case, the State Licensing Authority may use his discretion and duly record his observations.

**Action – All State Drugs Controller.**

**AGENDA NO. 33**

**CONSIDERATION OF THE QUESTION WHETHER PRODUCTS MEANT FOR EXPORT UNDER NEUTRAL CODE LABELING, CAN BE PERMITTED TO CARRY THE ADDRESS OF THE MANUFACTURER IN THE STATE OTHER THAN THE STATE WHERE THE PRODUCT IS ACTUALLY MANUFACTURED**

**Requests have been received by the Directorate, wherein the manufacturer intends the manufacture the drugs under code number where the product is actually manufactured, however on the label, they**

**intend to mention the name and complete address of their factory located in other State, mentioning as "Manufactured in India by……" contrary to the provisions laid down under sub-rule 2 of Rule 94 of the Drugs and Cosmetics Rules.**

**The above may please be deliberated to have uniformity in all the states.**

Under Rule 94 of the Drugs and Cosmetics Rules certain exemption are given from labeling and packing requirements of drugs for export which shall be adapted to meet the specific requirements of the Law of the country to which the drug is exported. The Rule however, provides that the following particulars shall appear in a conspicuous position on the inner most container in which the drug is packed and any other covering in which that container is packed.

a. name of the drug
b. the name, address of the manufacturer and the number of the licence under which the drug has been manufactured.
c. Batch or lot number
d. Date of expiry, if any:]

The proviso to Rule 94 provides that where a drug, not classified under Schedule F, Schedule F (1) Schedule X, blood products, Narcotic and Psychotropic Substances is required by the consignee to be not labeled with the name and address of the manufacturer, the labels on packages or containers shall bear a code number as approved by the Licensing Authority mentioned in Rule 21.

Where a Neutral Code is issued in respect of drugs meant for export purposes by the State Licensing Authority to whom this power has been delegated they shall ensure that it meets the specific requirements of the importing country. And also the manner in which the drugs are registered in the importing in the country. If the drugs have been registered with the name and address of the manufacturer were the unit is located there should be no objection in allowing the export with the Neutral Code and also the name and address of the manufacturer. Where however the address of the manufacturer is not that of that state where the manufacturer is located but is that of his registered office, in such case also, there may not be any objection for such exports. Where however the manufacture does not have is

manufacturing activity or the registered office in the address shown on the label of the container such export may not be permitted.

Action – All State DC's.

**AGENDA NO.34**

**CONSIDERATION OF THE QUESTION TO FIX DISTANCE BETWEEN TWO CHEMIST & DRUGGIST SHOPS/PHARMACY**

**A Committee was formed under the Chairmanship of Commissioner, Food and Drugs Administration, Gujarat, so that suitable provision can be made under the law to fix the distance between two retail Chemist & Druggist shops/pharmacies. However, no suitable provision has been made under the law till date. Therefore, the menace of mushrooming of Chemists & Druggists cannot be stopped, with the result all unethical practices are followed by many of the retailers, as it becomes very difficult for them to survive, if provision of the Drugs and Cosmetics Rules are followed.**

**The above may please be deliberated.**

While on deliberation, the Chairman informed that issue of fixing the distance between two chemist and druggist of shops/pharmacy had been discussed at various meetings of DCC in the light of representation made by All India Chemist & Druggist Association (AICOD). Earlier, a sub-committee was formed under the Chairmanship of Commissioner, FDA Gujarat. However, the recommendations of committee could not be accepted as it could attract the fundamental right of the citizen under constitution of India. Moreover, committee also recommended that the chemist shops should have stand by power system and refrigerator, which may further invite logistics problems.

During the discussion members were of the view that some common guideline be evolved to prescribe certain norms in regulating the sale license so as to strengthen the hand of Drugs Controller/Licensing Authorities. Members also apprised that many Pharma associations are pressurizing to make certain criteria for issuance of sale license, to curb the mushrooming growth.

The Drugs Controller of Kerala informed that in his state only diploma holders has been authorized for granting a sale license. The Drugs Controller Rajasthan, informed that granting of sale license is purely State subjects and state may have

prescribed their own procedure to tackle the menace of unchecked growth of Chemist Shops. Many members were of the view that legal opinion be sought before fixing the norms. After careful consideration of the view of members, the Chairman decided that proposal be referred back to the Commissioner FDA Gujarat, so that proposal be thoroughly reviewed through by the Sub Committee under his Chairmanship.

**Action – Sub Committee/Com-FDA Gujarat**

**AGENDA No.35**

**CONSIDERATION OF THE QUESTION TO GIVE SUITABLE TIME FOR WITHDRAWAL OF DRUGS FROM THE MARKET, AS AND WHEN IT IS BANNED UNDER SECTION 26-A OF THE DRUGS AND COSMETICS ACT OF late, it is seen that Rofecoxib was banned by the Government, vide Notification in the Official Gazette under GSR No. 810(E) dated 13/12/2004, which came into force with immediate effect. Since the ban came into force with immediate effect, it was very difficult for the officers to check the compliance of the said banned order. It is therefore requested that as and when such ban is imposed, at least four months notice should be given to withdraw the entire stock from the market by the manufacturers, as well as wholesalers/stockists/distributors, etc. Otherwise, media makes the issues of non-implementation of the ban order, which causes much embarrassment to the Regulatory Authorities.**

DCG(I) explained the members that earlier a time period was used to be given for phasing out the drug from the market in respect of drug banned under Section 26-A by the Central Government through a notification. However, a view was taken by the Hon'ble High Court of Delhi that if a drug is considered to be harmful then it should not be permitted to be sold after the notification. In view of the above it would not be possible to give a time period under the notification for the withdrawal of the stocks if the drug is considered to be harmful.

If was emphasized that during inspection of drug retailer or wholesaler, the Drug Inspector should keep a special check and mention in their report about their observation about stocking or otherwise of any banned drug.

**Action - All State DC's**

**AGENDA NO. 36**

**CONSIDERATIO FO THE QUESTION TO GRANT WHO APPROVAL WITHOUT INSPECTION, IN CASE THE PLANT IS APPROVED BY U.S. FOOD AND DRUGS ADMINISTRATION, T.G.A., M.H.R.C., ECT. AND APPROVAL OF THE MANUFACTURING UNIT BY WHO, GENEVA, FOR SUPPLY OF DRUGS TO U.N. AGENCIES.**

**It is seen that certain Drugs Control Authorities from different countries inspect the manufacturing units along with the experts from different fields, and on their recommendations, approvals like T.G.A., M.H.R.C., etc. Are issued. It is also noted that these authorities check the whole system of that plant in depth, and based on their recommendations, such approvals are granted.**

**It is proposed that in case any unit is approved by the said authorities, then, WHO-GMP Certificate, be granted without any inspection. Secondly, the validity of WHO-GMP Certificate should be increased to 5 years instead of 2 years, as it causes great hardship to the manufacturers who exports their product.**

The committee observed that presently the State Licensing Authority issues certificate of Pharmaceutical Products (COPP) after a joint inspection carried out by the officers of state & Central Drugs Control Deptt. As per WHO Guidelines, COPP is issued for a specific product & hence detail auditing of the particular Product is necessary alongwith other GMP facilities available at the Mfg. Site. The procedure followed by other international agencies may be site oriented or product oriented. Therefore, the committee is of the opinion that on the basis of GMP certificate issued by other international agencies, COPP should not be permitted without any auditing. However the audit team may consider the report of external agencies in this regard. But for Bulk Drugs, if the site is approved either by FDA (USA), TGA (Australia), MCA (UK) and South Africa, the State Licensing Authority may consider issuance of WHO GMP Certificate without further auditing.

The committee also opined that validity of COPP should be for two years which may be extended to maximum up to 3 years.

**All DC's / All Zonal /Sub-Zonal Office of CDSCO**

**AGENDA NO. 37**

**CNONSIDERATION OF THE QUESTION THAT SUITABLE AMENDMENTS SHOULD BE MADE UNDER SCHEDULE X OF THE DRUGS AND COSMETICS RULES**

**It is seen that Schedule X widely covers the psychotropic drugs, however, it is felt that the Schedule X should be updated, wherein potent drugs like psychotropic drugs, under the Narcotic Drugs and Psychotropic Substances Act, used for medicinal purpose as well as tranquilizers, sedatives, hypnotics, etc. Should be brought under the purview of Schedule X, in order to avoid misuse of the same.**

**The above may please be deliberated.**

The issue was discussed at length by the members of the committee. DCG(I) apprised the members that recently the Narcotic Control Bureau had taken a proactive rule in controlling the sale of Psychotropic Substances moving in the trade by insisting on the maintenance of a consignee note in Form 6 as required under the NDPS rules. The members of the Chemist Association went on a protest where by the availability of these drugs were greatly reduced and in some states the stockists/wholesalers/retailers stopped the stocking of these drugs. The consumers and patients were put to great difficulty and the matter was given wide publicity both in the parliament, press and the visual media. To sort out this embargo an interministerial meeting was called by the Ministry of Finance under the chairmanship of Home Secretary attended by the Narcotic Control Bureau, Ministry of Health and Drugs Controller General (India). It was decided in the meeting to amend the NDPS Act so as to waive of the requirement of consignment note in Forms 6. The DCG(I) further explained that bringing these drugs which are already in Schedule H to Schedule X will restrict its availability to the consumers and patients as there are very few licencees having Schedule X Licences. After further discussion it was agreed that at present there is no need to bring these drugs under Schedule X of the Drugs & Cosmetics Rules.

**AGENDA NO. 38**

**CONSIDERATION OF THE QUESTION TO LAY DOWN PROVISION WITH RESPECT TO CHEMISTS AND DRUGGISTS AND WHOLESALE PREMISES**

Due to advancement in the pharmaceutical field, all types of readymade medicines are available in the market and hence, hardly there are any pharmacies. Those pharmacies which were licensed earlier, have retained their name as "Pharmacy" without any compounding section and equipment as laid down under "Schedule N" of the Drugs and Cosmetics Rules.

In the entire Drugs and Cosmetics Rules, there is no provision for Chemists and Druggists and wholesale premises, except that of area.

As the consumers are becoming very vigil and they criticize the Regulatory Authorities every now and then, therefore, it is felt that in order to plug the loopholes, some of the provisions of "Pharmacy" should also be laid down for Chemists and Druggists as well as for wholesale premises. A few points are given here below:-

1. **Height of the Chemists and Druggists and Wholesale premises shall be atleast 2.5 meters**
2. **Floor shall be smooth and washable. Walls shall be plastered, tiled or oil-painted.**
3. **The premises shall be separate from the rooms for private use.**
4. **Drugs shall be sold under the continuous and personal supervision f Registered Pharmacist whose name and photo shall be displayed conspicuously in the premises visible to the consumers.**
5. **The pharmacist shall always put on clean, white overalls.**
6. **All psychotropic drugs, tranquilizers, sedatives, hypnotics and other drugs likely to be misused, shall be kept under lock and key.**

**The above may please be deliberated.**

After discussion the members agreed to refer the matter to the Enforcement Sub Committee for an in depth examination of the issue and to come out with relevant suggestion.

**Action – Sub Committee on Enforcement matter**

## HARYANA

**AGENDA NO. 39**

**TESTING LABORATORY FOR REPACKING UNIT**

**Rule 71-A provides conditions to be satisfied before grant or renewal of Repacking License in Form 25 B. According to Sub Rule (3) of the said Rule the applicant shall have adequate arrangements in his own premises for carrying out test for the strength quality and purity of testing unit, which shall be separate from the repacking unit.**

**Rule 74-A provides conditions for license in Form 25-B. According to the sub rule (b) of the said Rule, the licensee shall either provide and maintain adequate arrangements in his own premises for carrying out tests of the strength, quality and purity of drugs repacked or make arrangements with some institution approved by the Licensing authority for such tests to be regularly carried out on his behalf by the institution .**

**Thus, perusal of Sub Rules 71 A(3) and 74 A (b) indicates that there is an ambiguity in these Rules and they look like self contradictory. Drug Consultative Committee should look into the matter and take necessary steps for the removal of this ambiguity in these Rules. Technically speaking Sub Rule 71 A (3) and 74 A (b) should identical.**

The committee observed that there is an ambiguity in Rule 71 A(3) & 74A(b) which needs to be corrected. However, in the opinion of the Committee Rule 74A(b) is correct and accordingly Rule 71A(3) may be amended in tune with Rule 74A(b).

**Action – Office of DCG(I)**

**AGENDA NO. 40**

**LOAN LICENSING OF LARGE VOLUME PARENTERALS**

**Loan Licenses for products specified for a schedule C and C are issued under Rules 75-A, 76-A, and 78-A, incidentally all large volume parenterals also fall under category of Schedule C drugs. Some states are issuing Loan Licenses on Form 28 A without taking approval from Central License Approving Authority, which is mandatory under Rule 68 A. This has created a great confusion because in case of host firm the license is issued by Licensing Authority and finally**

**approved by CLAA but for a Loanee firm who is enjoying facilities on the same host firm, no such approval is required from CLAA. Even in additional products, in case of the host firms are granted after approval of CLAA but for Loanee firm they are sanctioned by SLA only. So this flaw in the law has to be rectified and if the loan licensing of LVP's is permissible then specific forms for applications and license should be prescribed for the loanee firms also. At present, there seems to be no such provisions in Rules and no forms have been prescribed for loan license in respect of large volume parenterals.**

DCG(I) explained the members that the Loan Licenses which are granted for the purpose of utilizing spare capacity of a licensed manufacturer and does not involve any manufacturing activity and the quality of the product is taken care of by the principal manufacturer who is already approved by SLA or the CLAA as the case may be. Requests were received from many State Licensing Authorities that the grant or renewal of Loan Licences for the manufacture of LVP's should be permitted by SLAs or separate provision should be created for processing such applications by CLAA even though it does not involve any establishment of a manufacturing facility. He added that CLAA undertakes the following activities before the approval of the Licence.

1. Verification of statements of the manufacturer in respect of manufacturing premises, technical staff manufacturing facilities etc.
2. Inspection of the establishment.
3. Acceptance or rejection of application on the basis of the report of the Licensing Authority.

All these requirements are practically non-existent in the case of the Loan Licences. It was therefore felt that a provision should be created in Rule 75-A and 78-A so as to facilitate SLA's for grant grant of Loan Licences for LVP's

After deliberations, DCC agreed to the proposal and recommended that Rule 75-A and 78-A may be suitable amended so that loan licenses for LVP's could be granted by the State Licensing Authorities. However, it was agreed that a formal NOC would be obtained from CLAA before processing any application for loan licensing any CLAA item.

**Action-All State DC'S/ Office of CDSCO**

**AGENDA NO. 41**

**GMP CERTIFICAT**

**Form 26 E-I has been prescribed u/s 157 (1-A) for Certificate of Good Manufacturing Practices (GMP) to manufacture of Ayurvedic, Sidha & Unani drugs but no such certificate has been prescribed for Modern drugs. However, the GMP certificates are invariably being issued to the manufacturers for the modern drugs.**

**So for making it Legal, necessary amendments should be made in part VII (u/s Rule 71,74 and 76) and a form should also be prescribed in case of modern drugs like as Form 26 E-I of Ayurvedic drugs.**

The Drugs Controller Haryana informed the committee that Form-48 E-1 is prescribed under section-157 (1-A) for certificate of GMP to manufacturer Ayurveda, Sidha or Homoeopathy madicines but no such certificate has been prescribed for the modern drugs. However, the GMP certificate are in variably being issued to the manufacturer by the various State Drugs Controllers, therefore, it is proposed to prescribe uniform format for GMP certificate.

While on deliberation, chairman informed that earlier the same issues regarding uniformity of the GMP certificate, non conviction certificate, free sale certificate, etc. Was came up as an agenda under NHRC issues and same was discussed in the special DCC held o 26.07.99 wherein a sub committee was formed to examine an frame common format which could be adopted by SLAs. Accordingly, the sub committee framed the various formats for use of SLA in issuing GMP certificate, non conviction certificate, free sale certificate, etc and same was accepted in the 33$^{rd}$ DCC Meeting held on 31.08.2000 at New Delhi. Further chairman informed that the copy of the each format will be again circulated along with the minutes for information. Copy of the formats are given at Annexure.1

**Action – Office of DVG(I)/ All State DC's**

## JAMMU & KASHMIR

**AGENDA NO.42**

1. **In order to curb the nexus of medical practioners and retail dealers of pharmaceutical, following rules needs to be incorporated after Rule 65 (21):**

**Sub – Rule NO. 22**

**The Licensee shall not utilize the services of a registered medical practioner to practice in his sale premises.**

**However, this shall not apply to RMP owned Pharmacy/Chemist & Druggist premises.**

2. **In order to curb the cross contamination of drugs with deleterious microbial substances, following rule is suggested to be incorporated after the above mentioned rules:**

**Sub Rule NO.23**

**The licensee shall not utilize his premises for any clinical testing purpose.**

Due to the absence of Drugs Controller J & K these items were not taken up for discussion. It was however felt that amendment in the Rules would not be pragmatic as these are policy issues at State level.

## ASSAM

**AGENDA NO.43**

**The cosmetic manufacturing in Rule 139(1) regarding qualification of chemist should be deleted from the present Rule and minimum Qualification should be specified as B. Parma/B.Sc. with chemistry with sufficient experience in the Mfg and list of Cosmetic (as now a days number of qualified personnel in pharmacy and pharmaceuticals products are coming up).**

After deliberation it was decided to amend the Drugs and Cosmetics Rules in order to prescribe bachelor degree in science (B.Sc.) as minimum qualification for the manufacture of cosmetics.

**Action – Office of DCG(I)**

## MAHARASHTRA

**AGENDA NO.44**

1. **Evolving standards for cosmetics products and regulation of tall claims made by cosmetics manufacturer.**

**Due to the evolution in the Cosmetics Industry more and more cosmetics product are being manufactured with product differentiation. Such product differentiation are made by issuing labels with tall claims associated with presence of various Ayurvedic ingredient, herbal extracts etc. Certain properties also proclaim on the label to increase the scalabilities of these products. (Deodorants, Prickly Heat, Anti-Septic, Fair and Clear skin ect.)**

**There are broad standards laid down for the manufacture of most the cosmetics but all these cosmetic are silent on the claims that can be make by the manufacturers. In these products the manufacturers are only require to declare the few names of the ingredients and are not required declare the full composition of the product giving the percentage of ingredients that are associated with the claim made in the product.**

**Section 17 C (c) of Drugs & Cosmetics Act, 1940 specifically prohibits market of misbranded product which make tall and misleading claims. It has been verified by the FDA from the BIS and form the Drugs & Cosmetics Act, that cosmetics products are licensed, based on the declaration of the composition made by the manufacturer. No proof of clinical trial or dermatological safety of these products are obtained from the manufactures. It is widely believe that the manufacturers are themselves responsible for the safety of such products and are supposed to maintain records in supports of the safety study and health and dermatological claims being made in respect of these products.**

**Following issues may be discussed by the Drugs Consultative Committee for amending rule 148 of the Drugs & Cosmetics Act, and for the issue of**

**appropriate guidelines under Rules 17 C (c) in respect of misbranding through advertisements in the electronic and print media.**

1. **All cosmetics products must have standards in respect of all the raw materials being used in manufacture of such product and also for the finished products itself.**
2. **The cosmetics products must have standard laid down for microbiological contamination.**
3. **All manufacturer of cosmetics product shall established dermatological safety of such products as per the standards to be laid down by the BIS.**
4. **All cosmetic products should disclose complete information to the consumer regarding the ingredients and also shall carry appropriate warnings on the likely side effect on account of use of products.**
5. **No cosmetics products shall be advertise or label in order to make any claim regarding the bebefit that shall accrue on account of such of such product unless such a claim is validated by a technical committee appointed DCG(I)/BIS. It shall be duty of such manufacturer to approach the committee and get the product cleared for the validation of claim made by him on the label of product. The DCG(I)/BIS shall however lay down the list of benefits accruing on account of normal use of every cosmetics product and for such claim no approval shall be necessary.**
6. **In case of cosmetic containing herbal ingredient BIS may evolve standards for manufacture of such cosmetics and also create a mechanism for validating the claims made by such manufacturers as per the procedure recommended above.**

   The above agenda was considered by the committee along with agenda no.1 which was also on the same subject.

2. **<u>Evolving standards for cosmetics products to be branded as Baby Cosmetic Products.</u>**

**Due to the evolution in the Cosmetics Industry more and more cosmetics products are specially being manufactured and are specially targeted to be sold as "Baby" Cosmetics products.**

**These products are being manufactured by leading multinational company and in view of the heavy advertisement in the Electronic and Print Media the public particularly the mothers buy this expensive products believing**

**that the products content ingredient that are good and healthy for the babies.**

**There are no standards laid down for manufacture of most "Baby Products" except for 'Baby Powder and Baby Soap". Even in these products the manufacturers are only require to declare the few names of the ingredients and are not required to declare the full composition of the products giving the percentage of individual ingredients in the product.**

**Section 17 C (c) of Drugs & Cosmetics Act, 1940 specifically prohibits market of misbranded product, which makes tall and misleading claims. It has been verified by the FDA from the BIS and form the Drugs & Cosmetics Act, that cosmetics products are licensed, based on the declaration of the composition made by the manufacturer. No proof of clinical trial or dermatological safety of these products are obtained from the manufactures. It is widely believe that the manufacturers are themselves responsible for the safety of such products and are supposed to maintain in support of the safety study and health and dermatological claims being made in respect of these products.**
**Since the licensing of the products is left to the Drugs Officers in the State level there is great variation in the manner in which licenses are issued by the Drugs Officers for the manufacture of these products. Further because of shortage of technical manpower and absence of uniform guidelines the licenses are routinely issued for the manufacture of all types of cosmetics product including baby cosmetics product in both Allopathic as well as Ayurvedic category. No guidelines have been issued by the Drugs Controller of India in respect of labelling of such product and in respect of any claim that the manufacturer wishes to make in the usage of these products.**

**The facts become particularly important when we deal with manufacturing and sale of baby product on account of the hyper sensitive and tender skin of the babies. It is further seen that in this country we have long tradition of preparing baby application products using naturally obtained commodities like, Sandal Wood, Vegetable Oils, Turmeric, Sikekai, Besan, Mungdal Poweder alongwith Herbal Ayurvedic Tulsi, Neem, Bramhi, Amala, etc. In their pure form or in mixture with or an extraction in to Water, Milk , Honey etc. Our values and tradition have been time tested and accepted safe and effective for the baby care. Particulary for massaging babies, washing baby skin, applying in the head, sole and so on. Due to**

**organisation and difficulties in getting all these ingredient in sufficient quantity in the country mothers particularly find it attractive go for readymade baby care product believing that these products are equivalent to those made traditionally. These belief stem from the repeated bombarding of tall claims by the manufacturers of the synthetic cosmetics products by using electronic and print media. Since the cosmetics lawas at present do not require the manufacture to declare complete formulation of his cosmetics products alongwith its limitations consumers fall pray to marketing gimmick of the companies and pay fancy prices to purchase cheap synthetically made cosmetics for the babies. This is further compounded by the unethical marketing practices by the manufacturing companies by offering incentives and allurements to doctors and chemist alike foreign trips, gifts, high commission etc. We believe that children do no need cosmetics and if they need the parents should make a carefully weighted decision after getting full and complete information of the products regarding its usefulness, complete, limitations in the use such products warnings to accompany the sue and so on.**

**We therefore request that the following issues must be discussed by the Drugs Consultative and recommended to DTAB for amending rule 148 of the Drugs & Cosmetics Act, being incorporated in the Drugs & Cosmetics Rules and for the issue of appropriate guidelines under Rules 17 C (c) in respect of misbranding through advertisement in the electronic and print media by the Drugs Controller of India.**

1. All baby cosmetics products to be labelled as “Baby Cosmetics Products” must have standards in respect of all the raw materials being used in manufacture of such product and also for the finished products itself.

2. The baby products must have standard laid down for microbiological contamination.

3. **All manufacturer of baby product shall established dermatological safety of such products as per the standards to be laid down by the Drugs Controller of India.**

4. **All baby products should disclose complete information to the consumer regarding the ingredients and also shall carry appropriate warnings on the lightly side effect on account of use of products.**

5. **No baby products shall be advertise or label in order to make any claim regarding the benefit that shall accrue on account of such of such product because it is generally believed that no chemical should be applied to the babies except under medical supervision for the treatment of any medical condition.**

6. **No baby products shall be advertise / label in such way as to lend its comparison with any traditionally made or used product unless and until such comparison established before the licensing authority.**

**It is further suggested that the joint committee of experts in the field of Pharmacology, Pediatrics and Dermatologists and regulatory officers from the state and the Central Government and form the BIS may be constituted to lay down detailed guidelines and standards for each of suggestion as refer to above.**

**It is further suggested that, until such guidelines and standards are laid down by the Central Government under the Drugs & Cosmetics Act no manufacturer should be permitted to market his any cosmetics products with the prefix 'Baby'**

Discussed vide agenda item no. 1.

**3. <u>Approval of proprietary Allopathic Medicines in the State-Need for common guidelines and adherence to the Drugs & Cosmetics Act and Rules.</u>**

**The allopathic medicines in the country are manufactured as per the provisions of Drugs & Cosmetics Act. Every drug formulation in the country needs to be licensed for manufacture by the respective Drugs Controller in the State. However, drugs can be manufactured in any of the 35 States and Union Territories for being sold throughout the country.**

When drugs formulations are made in accordance with one of the Pharmacopoeia viz. IP, BP, USP etc. it becomes easy to analyze the drug as per the pharmacopoeia even through the drug might have been manufactured at any location in the country. Further

these are established drugs for their standards, safety & efficacy. With the Government of India implementing Schedule 'M' guidelines in the State, we can say that the Pharmacopoeial drugs are more or less standardize for the manufacturing and also for the testing in order to ascertain its genuineness and efficacy.

However manufacturers are turning to the area of proprietary drug formulations. Every proprietary drug formulations must be manufactured and validated in accordance with the Rule 71 and 76 of the Drugs & Cosmetics Rules for the non-biological and biological products respectively.

However in practice we see that most of the manufacturers do not have the manpower, the resources or capacity to conduct these studies properly and the proprietary formulations are approved based on some routine data and are not validated or subject to scrutiny by the expert body. Most of the times the products are license because similar products are in the market. The safety, stability, efficacy and shelf life of these products are therefore not evaluated uniformly.

Thousand formulations licensed for manufacture even though pharmacopoeia formulations are around one thousand .

In order to curb the mushrooming number of non-pharmacopoeial preparations and vitamin preparations coming under Schedule 'V' we make the following suggestions for the consideration of the DCC.

1. There shall be 'Standing Committee' comprising of experts from Pharmacologist, Biopharmacutics and regulators from FDA, CDSCO apart from statutory bodies like ICMR, IPA.

2. The standing committee shall scrutinize the data submitted by the manufacturer of patient and proprietary drug which are justified by the scrutiny for the stability safety and efficacy of use as drug. The committee in particular should also examine the rationality and therapeutic justification of such a drug including bio equivalence/bio-availability of the drug in the fixed dose combination. The committee should also scrutinize the medical literature to be circulated by the data to be maintained and submitt4ed to the committee by the manufacturer. Every patent and proprietary medicine should be licensed initially for 2/3 years and only after validation of its efficacy from the post market surveillance data including adverse reaction report, stability, shelf life etc. That the manufacturing of the medicine should be allowed to be continued further.

3. No patent and proprietary drug shall be licensed for manufacture by any of the Drugs Controller unless he produces the necessary clearance from the standing committee in respect of the drug he propose to manufacture.

4. All the existing formulations should also be subject to scrutiny by the expert committee and given the large number of these formulations this exercise can be made by appointing subcommittee drawn from members from for each state.

The Chairman informed the members that presently there are no system like Central registry of all approved formulation in the country. There are about 9000 drug manufacturers. Even if every firm market 10 drug formulations, there may be about 9000 brands in the market. However many of these would be brands of same proprietary or Pharmacopoeial formulation. Since large number of formulations are available in the country, there is need of a Central registry. Initiative is being taken by Central government through Computerization Programme to link all States licensing authorities. However, the State Licensing Authorities have to play a very responsible role to ensure that powers given to them are not misused. This bas caused serious aberration already.

The Chairman also explained in brief the procedure followed for “new drug” evaluation before its approval. Such products are examined extensively for their clinical relevance, rationality, published clinical trial reports, regulatory status etc. Based on the relevant data evaluation, in consultation of subject experts, the firms are asked to conduct well design clinical trial and bioequivalence studies to established efficacy and safety of the product. Even for fixed dose combination formulation of drug already in use, these parameter are followed.

However, the States Licensing Authorities are perhaps granting the manufacturing license to such products because similar products are available in the market. He pointed out that many of these so called similar formulations available in the market might not have been actually approved by DCG(I). He agreed with views of commissioner FDA Maharashtra that the safety, stability, efficacy and shelf life these products are therefore questionable. There is also a revenue loss to central government, as required amount of fees may not have been charged. He also informed the member about the steps taken by Central Govt. by way of issuing directive under Sec.33 P, and amendment of Rules etc.

It was agreed by the committee that in future, if any information regarding issuing a license to the product without DCG(I) approval is sought from the concerned SLA, response is to be received within 15 days, failing which the DCG(I) would take up the matter with higher ups in the States for their intervention to fix responsibility for deviating from the Rules. This issue has to be taken a serious note of by all State licensing authorities.

## TAMIL NADU

### AGENDA NO.45

**1. Plea under Section – 19 (3)**

Section 19 (3) provides for pleas that can be availed by a person to avoid penal action under Drugs & Cosmetics Act. Section 19(3) specifies that a person shall not be liable for prosecution for contravention of section 18 of Drugs & Cosmetics Act. The work Section 18 is wide and it also includes contravention of Section 18 (c) for which section 19(3) cannot be applied. Hence it is suggested that for the words Section 18 in Section 19(3) shall be substituted with the words "Section 18 except Section 18 (C)"

**2. Rule 64**

**Condition to be Satisfied before grant of license**

This rule requires that the applicant has to satisfy the Licensing Authority with reference to the adequacy of premises. The word premises does not exclude residential areas, which creates practical problem at the time of rejection of application. This requires to be suitably amended to exclude the residential premises.

**3. Rule 74 A**

Rule 74 A of Drugs & Cosmetics Rules specifies the condition of license in F. 25 B. As per this rule the licensee need not require to maintain the records of manufacture as required under 74 (d) for licensee in form 25 & 25F. This has to be included in rule 74-A.

**4. Rule – 74 B**

Rule 74 B of Drugs & Cosmetics rules specifies the conditions of license in F.25 A. As per this rule the licensee need not require to maintain the records of manufacture as required under rule 74 (d) for licensee in form 25 & 25 F. This has to be included in rule 74 B.

**5. Rule – 78 A**

Rule 78 A of Drugs & Cosmetics rules specifies the condition of license in F.28 A. As per this rule the licensee need not require to maintain the records of manufacture as required under rule 74 (d) for licensee in form 25 & 25 F. This has to be included in rule 78 A.

**6. Rule 96 (1) (viii)**

Labelling of Imported Drugs. It specifies labelling provisions only for Sch-C (I) Drugs. The rule has to be amended for all classes of drugs.

**7. Rule 96 (1) (iv)**

Rule 96 of Drugs & Cosmetics rules prescribe the manner of labelling of drugs including drugs manufactured by loan licensee. Rule 96 (1) (iv) requires that name of the manufacturer and address of the premises of the manufacturer, where the drug has been manufactured has to be specified. In practice, It has been observed that whenever a memo is issued to the address (manufacture at) mentioned on the label it is always returned as "no such address". Hence it is suggested the said rule may be amended suitably as "name (and address) of the manufacturer"

**8. Rule 69 (5)**

Rule 69 (5) may be suitably amended as of Rule 75 (5)

**9. Rule 150-K Specifies**

Withdrawal and suspension of approval of Form-37.
There is no penal provision of issuing test reports during the period of suspension. Hence penal provision has to be incorporated.

**Schedule – A**

**FORMS**

**1. 19 and 10 – C**

In Form 19-2 and in form 19- C-2. "The sale and dispensing" may be changed as "The same/dispensing" Further the words "competent person" may be included after qualified person.

**2.** In Forms 20B, 21B, 20F, and 20G. 3rd para as of Form 20 and 21 has to be incorporated.

**3.** Forms **20B, 21B**

**In condition 3 (ii) (b) the words a hospital, medical has to be removed since the Sch 'K' has been amended to delete the hospital etc.**

**4. Form 20 - G**

**In Forms 20 – G after para 3 " names of qualified person/competent person in charge" to be invorporated.**

**5. For Blood Starafe Centres ( as oer SL.No. 5B of Sch – K) Fees and Forms to be prescribed.**

As Tamil Nadu, Drugs Controller did not attend the meeting their agenda could not be taken, However, Chairmen informed the members the agenda pertains to Tamil Nadu are of minor changes required in Drugs and Cosmetics Act and Rules. The office of DCG(I) will examine the proposal and taken necessary action.

**Action – Office of DCG(I)**

**AGENDA NO. 46**

**ISM DRUGS**

**1. Sch – T – Rule 157**

**Rule 157 Drugs & Cosmetics rules requires the manufactures of drugs shall be carried out in such premises and under such hygienic condition**

**as per Sch T. It does not include the compliance to the other provisions of Sch. – T. The reading of Rule 157 – (A) makes it to look as of only for the purpose of GMP certificate Sch – T shall be complied with. Hence for better enforcement of quality of ISM Drugs and to maintain the prestige of drugs manufactured in India above suggestion for all compliance of schedule T may be included.**

2. **New Fee Structure Prescribes Rs. 1,000/- for grant of license. Whereas for renewal it prescribes Rs. 1200/- this anomaly has to be rectified.**

3. **Sch – T Part II**

   **Specifies area is 1200 Sq. Feet. This has to be converted into metric system.**

   As these items pertain to ISM department, the proposals have been forwarded to them for necessary action.

**AGENDA NO. 47**

**DMR**

**Present DMR does not include Advertisement made through Electronic Media. This has to be amended.**

DCC was informed by the Chairman that the Drugs and Magic Remedies (OA) Act 1954 is proposed to be amended and the advertisements made through electronic media are proposed to be covered under the Act.

**WEST BANGAL**

**AGENDA NO. 48**

**Proposed amendments to the Drugs and Cosmetics Act, 1940 and Rules, 1945**

I. **Certain offence to be made compoundable 30AA.**

**(1) Notwithstanding anything contained in the Code of Criminal Procedure all offences except offences under Section 27 (a), 27 (b), 27 (c), 27A(i) and 28B of the Act shall be compoundable.**

**(2) The authority to compound the offence shall vest with the appellate authority appointed under Section 21A of the Act.**

A Bill has already been introduced in the Rajya Sabha to amend various penal provisions in the Act, which indicates compounding of offences and provisions for special designated court.

II. **Amendment to define spurious and counterfeit drugs separately (A) Spurious drugs – Clause (a) and clause (b) in Section 17 B shall be deleted and clauses (c), (d) and (e) shall be renumbered as clauses (a), (b) and (c).**

**17BB. Counterfeit drugs :- for the purpose of this chapter a drugs shall be deemed be counterfeit (a) if it is manufactures under a brand or trade name which belongs to or is owned by another manufacturer. (b) If it is an imitation of, or resembles another dugs in a manner likely to deceive or bears upon it or upon its label or container the name of another drugs unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drug:- Provided that a drug shall not be deemed to be counterfeit unless the trade name or brand name rights are clearly decided in favour of one manufacturer by the competent authority under the Trade Mark Act or by the Court.**

The Committee is of the opinion that the present definition of spurious drug under section 17B is sufficient to define the counterfeit drug.

**III. Amendments to define branded drugs**

**In section 3 new clause (i) shall be inserted stating? Branded drug means any Pharmacopoeial or Patent and proprietary medicine manufactured and sold under a trade/brand name?**

The committee is of the opinion that no action is warranted in this regard.

**IV.Powers of Drugs Inspectors**

**22AA Power to examine persons- Any Drugs Inspector specially empowered in this behalf by general or special order of the Central or State Government may, during the course of any enquiry in connection with manufacture, sale or distribution of spurious or adulterated drugs or cosmetics-require any person to produce or deliver any document or thing relevant to the enquiry:**

**(a) Examine any person acquainted with the facts and circumstances of the case.**

22AAA Power to summon person to give evidence and produce documents.

(1) Any Drugs Inspector empowered in this behalf by general or special order of the Central or State Government shall have power to summon any person whose attending he considers necessary either to give evidence or to produce a document or any other thing in an enquiry, which such officer is making in connection with manufacture, sale or distribution of spurious or adulterated drugs or cosmetics.

(2) A summons to produce documents or other things may be for the production of certain specified documents or things or for the production of all documents or things of a certain description in the possession or under the control of the person summoned.

(3) All persons so summoned shall be bound to attend either in person or by an authorized agent as such officer may direct: and all persons so summoned shall be bound to state the truth upon any subject, respecting which they are examined or make statements and produce such documents and other things as may be required.

(4) Every such enquiry as aforesaid shall be deemed to be a judicial proceeding within the meaning of section 193 and section 228 of the Indian Penal Code (45 of 1860).

The Committee is of the opinion that no action is required in this regard as the current provision can address the concern to some extents. However, these issues could be examined by the legal Sub-Committee.

**Action - Office of DCG(I)**

**Vi. Amendment of Rule 49A (ii) & 50A (ii)**

*******experience in I) at least five years experience in enforcement of the Act. Or ii) at least two years experience in enforcement of the Act and at least three years experience in manufacture and /or testing of drug from a) Statutory laboratory or b) quality control laboratory of a licensed Pharmaceutical unit or c) Drug testing laboratory approved by the licensing authority.**

**Experience in the manufacture or testing should be omitted.**

The Committee is of the that the matter may be referred to legal Sub Committee to examine the issue in details

**Action – Sub-Committee on legal matter.**

**VII. Applicability of Section 451 of Code of Criminal Procedure (return of seized drugs during pendency of trial)**

**If the drugs are seized from an unlicensed premises and kept in the custody either at the place occurrence of suspected offence or in the custody of a malkhana of a police station, the whole stock of the drugs should not be returned to any claimant on any condition like cash bond or sale proceed even though the samples taken at the time of raid are declared of standard of quality by the Government Analyst applying Section 451 of Cr.P.C. on the ground of national wastage, as the efficacy of the drugs depend on the proper scientific storage condition which cannot be expected in the places as mentioned above. If returned and sold that consumers will not be aware of the fact that the drugs were not stored in proper storage condition.**

**The suitable provisions should be made in the Act so that Section 451 of Cr.P.C. cannot be applied in the cases of drugs, keeping in mind that there is every possibility of public hazard.**

**Provisions should also be there to protect the innocents from the unnecessary harassment.**

The Committee is of the opinion that the matter may be referred to legal Sub-Committee to examine the issue in details.

## DELHI

**AGENDA NO. 49**

**PRUNING OF SCHEDULE H**

**There are certain Schedule H drugs, which are sold by the retail chemists without prescription because of their popularity and socio-economic conditions prevailing in the country. The regulatory agencies are often blamed for non-implementation of the law in this regard. It may be mentioned here that the problems which have socio-economic and cultural dimensions cannot be solved with law and enforcement agencies only. In view of this, the Schedule H to the Drugs & Cosmetics Rule 1945 may be pruned and some of the items under Schedule H can be taken out and may be placed under another Schedule. Such drugs may be permitted to be sold under the advice or in consultation with the Registered Pharmacist. The drugs which can be considered for this purpose could be:**

i) **Non-steroidal anti-inflammatory drugs (NSAID) like ibuprofen, diclofenac sodium, mefenamic acid etc.**
ii) **Antacids like Cimetidine, Ranitidine, Suceralfate etc.**
iii) Anti diarrhoeal drugs like halogenated hydroxy quinoliners: loperamide, diphenoxylate, metronidezole etc.
iv) Ophthalmic/Otic preparations containing antibiotics and/or steroids.

**Some restrictions may also be considered by the committee such as that the sale of these drugs will be restricted to only one time treatment/dispensation.**

The Chairman in principal agreed with above view. However he pointed out that it is enforcement issue. He also informed that draft Schedule H is currently under examination and it is possible to increase or decrease the number of drugs at this point of time. He raised his concern that if drugs are taken out of Schedule H. there are chances of their indiscriminate use.

After discussion on the issue, members agreed upon to take up the matter to the relevant sub-committee of DTAB.

**Action – Office of DCG(I)**

## AGENDA NO.50

## EXEMPTION TO MEDICINAL GASES

**Medicinal gases are often manufactured in the same plant where the gases for other commercial use are produced. There have been some instances in Delhi where the distributors of medicinal gases were not found having drug license. The gases in metallic cylinders occupy large space. As such, these are seldom stocked by retail chemists. Many a times, complaints are received from consumers about non-availability of medicinal gases from retail chemists. Since, the medicinal gases are either used in hospitals, nursing homes or under the medical supervision of a doctor, harm to consumer is not likely, if the exemption is given to the medicinal gases under Schedule 'K' from the sale license.**

The Committee was informed that a notification in this regard could soon be issued both for stocking and institutional manufacturer.

**Action – Office of DCG(I)**

## AGENDA NO. 51

## RATIONALIZATION OF LABELING RULES

**Under the present rules, a lot of information is required to be given on the label of a medicine. To accommodate the information on the label, the print size often is so small that** it can not be read with 'Naked Eye'. Therefore, the drugs which are required to be sold on the prescription of a RMP, should contain only particulars like batch number, manufacturer's name and address which will be helpful in tracing back the origin of the drugs, date of expiry and distinguishing mark for prescription drugs "Rx". The rest of the

Information can be given either by physician or pharmacist. While on those drugs where prescription is not required, the information useful to the consumer regarding its

use and precaution, if any, should be given on the label of carton. If the packing of non-prescription drugs is small and the intended information cannot be accommodated on inner carton, the information should be given on a leaflet or package insert for that consumer, if literate can read the information before use.

Committee felt that it is complex issue as many consumer organizations, on the other h and ask for more and more information to be provided. It was therefore decided to have the issues examined by the committee on enforcement maters.

**Action – Enforcement Sub committee**

**AGENDA NO. 52**

**LABELING OF COSMETICS**

**Many a times, Govt. Analyst declares a cosmetic as mis-branded for the reason that particulars required to be given under Indian Standards are not printed by the manufactures. The Drugs & Cosmetics Rules lay specific provisions relating to labelling of cosmetics. However, the rules are silent the cosmetics are required to comply with the Indian Standards but labelling is not a part of the standards and therefore, is not mandatory. The labelling requirements under Indian Standard will be mandatory only, if a cosmetics is marketed with ISI mark.**

**In view of this, a provision may be introduced under the rules to provide for inclusion of labelling requirements mentioned under the Indian Standard by cosmetic manufacturers.**

DCG(I) explained the members that the Rule 148 of Drugs and Cosmetics Rule is being amended and has already been discussed under Agenda No.1. It has been recommended that specific labelling requirement, if any, prescribed under BIS standards should also be made mandatory under Rule 148 of the Drugs and Cosmetics Rule.

**Action – Office of DCG(I)**

**AGENDA No. 53**

**INCONSISTENCIES/ERRORS IN THE RULES**

i) Under Rule 122P of the Drugs & Cosmetics Rules, 1954, conditions of license to be granted on Form 28 C have been described. As per sub rule (viii) 'no batch/unit manufactured under this license shall be supplied / distributed to a person without prescription of a RMP' meaning thereby that whole human blood IP or any its components cannot be supplied/distributed to person without the prescription of **a**

**RMP. It is, therefore, suggested that the words whole human blood IP and any of the blood component should be included under Schedule H.**

After discussion it was agreed that there is no necessary to amend the Drugs and Cosmetics Rules a the provision is adequate.

ii) **Under Form 35 given under Schedule-A the following figures and letters have been mentioned**

**"See Rules 65, 67-G, 74, 74-A, 74-, 78, 78-A, 85-H, 142, 142-A, 158 and 158-A. The following words are, however, missing which should also have otherwise appeared.**

**"122P, 150E, 142B.**

**Further the figure and letter 142A should be omitted since under the said rule additional information is to be provided by an applicant for license etc and has no relevance to the inspection report.**

DCG(I) stated that the proposal was for harmonizing the Form 35 of the Drugs and Cosmetics Rules werein reference to Rules 122P, 150 E and 142 B was required to be added and reference to Rule 142-A was to be omitted.

**iii) In Form 17-A under Schedule A of the Drugs & Cosmetics Rules reads as under:**

**"Whereas it, this.....day of.....,19.....Have taken.....It is suggested that the numerals 19 should be substituted with the numerals 20 since we are already in the 21st Century.**

**iv) Rule 144 of the Drugs & Cosmetic Rules, 1954 prohibits use of certain colours which are not prescribed. The said rule reads as under:**

**"No cosmetics shall be manufactured which contains Dyes, Colours and Pigments other than the one specified by the Bureau of Indian Standards (IS; 4707 Part I as amended) and Schedule Q".**

**It is suggested that the word 'and' appearing between Bureau of Indian Standard and Schedule Q should be substituted by the word 'or' which will make this prohibitory clause more specific.**

Form 17 A of the Rules was also required to be amended similarly for changing the numberals from 19 to 20 pertaining to the year because of change in the century.

DCC agreed that the above amendment may be made in the Drugs and Cosmetics Rules to remove the inconsistencies pointed out by Drug Controller Delhi.

**Action – Office of DCG(I)**

**6. SUPPLEMENTARY AGENDA**

**CENTRAL ITEMS NO. (1)**

**CONSIDERATION OF THE PROPOSAL TO DELETE PROVISIONS APPLICABLE TO THE PRODUCTION OF BIOLOGICAL PRODUCTS UNDER SCHEDULE F (1) TO THE DRUGS & COSMETICS RULES, 945.**

**Schedule F (1) to the Drugs & Cosmetics Rules, 1945, under its different parts (Part I, Part II, Part III, Part IV) prescribes provisions which are applicable to the production of Bacterial Viral Vaccines: Anti sera form living animals and provisions applicable to the manufacturer and standardization of Diagnostic Agents (Bacterial Origins).**

**A perusal of these provisions in various in parts would reveal that these are special conditions which, relate to conditions of manufacture besides different standards by an large, in the form of "monographs" in respect of preparations meant for humans and animals.**

**DDC may kindly deliberate if these could be deleted from the said Rules and are appropriately incorporated in other Book of Standards.**

The Chairman informed that under schedule F (1) to Drugs and Cosmetics Act, standards have been prescribed for Bacterial/Viral vaccine/Sera & Diagnostics kits, for Veterinary use. Consequent to the introduction of IP veterinary 2000 (Supplement to IP) many of such standards have now been incorporated in official book and therefore, it was proposed to delete the schedule F (1) in order to avoid repetition.

During the discussion the Director IVRI informed that many State Veterinary Biological units are still producing vaccines as per conventional standard prescribed in schedule F (1) and therefore before deleting the schedule F (1) in total, a careful examination of List of Biological provided in Schedule F (1) vis a vis IP Vet. Supplement is to be required. Accordingly the Chairman decided that proposal be referred to Director IVRI for examination and submit his views/ comments within six-month time.

**Action – Director IVRI**

**IVRI**

**AGENDA No.(2)**

**Proposal to include veterinary expert under the Rule 68 (4) of the Drugs & Cosmetics Act, 1940.**

**There is a great concern over the functioning of State Veterinary Biological Units in particular. There are about 20 State Veterinary Biological Product Units and 7 private Veterinary biological manufacturers. IVRI is playing a major role both in the regulation and controlling the matters of drugs for veterinary by way of DCG(I) and Department of Animal Husbandry & Dairying, Ministry of Agriculture. After joint- inspection of some of State veterinary Biological Products, and idea could be formed about present status of the firm. There is equally a need for joint-inspection of private veterinary manufacturers also. It has been observed that earlier either the inspection has been done without a veterinary drugs and vaccines is a specialized subject. With our efforts the Department of Animal Husbandry & Dairying, Ministry of Agriculture, GOI, New Delhi, has provided funds to the turn of Rs. 1 crore or so allowing these old State Veterinary Biological facilities for up gradation to raise their GMP status. Government Analyst at IVRI has also been apprising the staff about the concept of GMP/GLP whenever he is getting an opportunity.**

**In case of veterinary biological products units, we propose that the word "without" should not be considered rather an expert be involved having particular experience of GMP and other drug regulatory issues. This can easily be met out by the IVRI. Therefore, an insertion to this effect is proposed in the Rule 68.**

While explaining the agenda, the Director IVRI informed that there are about 20 state biological product units and 7 private biological product unit for the production of Veterinary/Poultry Biological s in the country and IVRI is playing major role in regulating both in terms of its production and quality control. Further, under the rule 68A, it has been prescribed that joint inspection of unit with or without expert should be carried out at the time of approving the license. Since Veterinary biological product is a specialized product, the veterinary expert be co-opted in the joint inspection team. During the discussion, the Chairman informed that vaccine/sera being a specialized science, therefore, rules has been prescribed for joint inspection with or without expert. However, due to the limited number of vety. Expert available, some time joint inspections are performed without expert on case to case basis. The Chairman, requested Director IVRI to furnish the names of few vety. Experts along with their qualification and area of specialization so that their services could be utilized for processing the licensing application etc in different parts of the country.

**Action – Director IVRI**

**AGENDA NO. (3)**

**PEOPOSAL TO REMOVE DEFICIENCIES IN INDIAN VETERINARY PHARMACOPOEIA (VET SUPPLEMENT 2000)**

**Our proposal for removal of deficiencies in the Indian Pharmacopoeia (Vet supplement, 2000) approved by 35th Drugs Consultative Committee, held on 29th & 30th April 2004 are yet to be made public by an official publication. Consequent to the formation of Central Indian Pharmacopoeia Commission, the procedure for issues relating to veterinary drugs and biological needs to be clarified.**

DCG(I) apprised the members that since Indian Pharmacopoeia Commission has been formed, the deficiencies in I.P. Vet 2000 approved in 35th DCC meeting would be forwarded to I.P. Commission for making addendum in this regard.

**Action – I.P. Commission.**

## DELHI

**AGENDA NO. (4)**

**MICROCIOLOGICAL LIMITS IN COSMETICS**

**Schedule S to the Drugs & Cosmetics Rules provisions that cosmetics in finished form shall confirm to the Indian Standards Specification laid down from time to time by the Bureau of Indian Standards (BIS). The Indian Standard specifications (BIS), now in vague, include among other parameters the requirement of microbiological examination of cosmetics. The cosmetics which are required to be examined for the microbiological quality include the following:**

| Sl No. | Name of cosmetics | Microbiological examination |
|---|---|---|
| 1 | Lipstick | Nmt 100 micr-og/gm |
| 2. | Tooth Powder | Cfu/gm(max)- 1000 |
| 3. | Tooth Paste | Microbial count<br>Total viable count per Gm nmt 1000 |
| 4. | Skin creams | Microbial content/limit total viable count Cfu/Gm-nmt 1000<br>Gram negative pathogens<br>Less than 1 0 |
| 5. | Hair creams | Nmt 1000 micro-org/gm |
| 6. | Skin powder | Microbial content limit<br>Total viable count<br>Cfu/gm nmt 100<br>Gram negative pathogens<br>less than 10 |
| 7. | Skin powders for infants | Microbial content limit<br>Total viable count<br>Cfu/gm nmt 100<br>Gram negative pathogens-absent |
| 8. | Hair oils | nmt 1000 micro org/gm |

**The microbial limits prescribed above can be obtained only when the design and construction of the building is such that it will result in lower bio-burden and also the cosmetics manufacturer take appropriate measures to reduce bio-burden in manufacturing areas. To achieve this objective, the requirements of factory premises for manufacture of cosmetics prescribed in Schedule M-II need amendment. DCC may discuss the matter.**

DCC agreed with the proposal of Drugs Controller Delhi on Microbiological Limits in Cosmetics. It was decided that during course of inspection of cosmetic units the test protocol followed as well as the manufacturing protocols followed by them should be scrutinized by the inspecting staff.

DCC sub committee on enforcement matters may examine the matter in details so as to recommend modifications/improvements to be introduced in Schedule M-II.

**Action – Sub committee of Enforcement matters**

## Concluding Remarks and Vote of Thanks

The members placed on record their appreciation for the staff of the office of DCG(I) of making excellent arrangement for holding the meeting. The meeting ended with vote of thanks to the Chair.

## CONSTITUTION OF SUB COMMITTEES OF DCC

It was also decided in the meeting that the Sub Committee on Legal issues and Sub committee on Enforcement issues constituted in the 35th DCC meeting held on 29th & 30th April, 2004 would continue to function and deliberate on specific issues, which have been indentified by DCC. The conveners would arrange for the meeting and finalize the recommendations of the subcommittees for consideration of DCC. Experts (S) deemed appropriate, may be co-opted by the sub committees.

**ANNESURE-I**
**AGENDA NO.41**

**GOVERNMENT OF_____**
**DRUGS CONTROL ADMINISTRATION**

Office of Director
Drugs Control Administration

Rc. No. 2000 Dated

**G.M.P. Certificate**

This is to certify that M/s._____ Situated_____ State are holding Licences in Form_____ bearing No._____ dated_____ valid upto _____ for manufacture for sale or distribution of drugs approved by this Department. The firm is subjected to periodical inspection by this Department.

2. The firm, by and large, is following GOOD MANUFACTURING PRACTICES as stipulated under the provisions of Schedule "M" of Drugs and Cosmetics Rules, 1945 is respect of the following drugs.

3. The firm should, however carry out self inspection from time to time to ensure that the requirements of GOOD MANUFACTURING Practices are complied with.

4. This certificate is issued on the request of the firm for the limited purpose of submitting the same_____ in connection with participating in the Tenders.

5. This Certificate is valid for One year from the date of issue.

Director
Drugs Control Administration

To
M/s.