डॉ. स. ईश्वरा रैड्डी एम.फार्म,पीएच.डी.
औषधि महा नियंत्रक (भारत)
केन्द्रीय औषधि मानक नियंत्रण संगठन
स्वास्थ्य सेवा महानिदेशालय
स्वास्थ्य एवम् परिवार कल्याण मंत्रालय
भारत सरकार
एफ. डी. ए. भवन, कोटला रोड़,
नई दिल्ली-११०००२

सत्यमेव जयते

Dr. S. Eswara Reddy M.Pharm, Ph.D.
Drugs Controller General (India)
CENTRAL DRUGS STANDARD CONTROL, ORGANISATION
DIRECTORATE GENERAL OF HEALTH SERVICES
MINISTRY OF HEALTH & FAMILY WELFARE
GOVERNMENT OF INDIA
F.D.A. BHAWAN, KOTLA ROAD,
NEW DELHI-110002

F. No. X-19013/04/2018-DC **Dated:** 20 **-02-2019**

To

All State/UT Drug Controllers

Sub: Minutes of the 55th Meeting of the Drugs Consultative Committee held on 31.01.2019 and 01.02.2019 at New Delhi - reg.

Sir,

55th meeting of the Drugs Consultative Committee was held on 31.01.2019 and 01.02.2019 at FDA Bhawan, Kotla Road, New Delhi-110002.

The minutes of the 55th meeting of the Drugs Consultative Committee is annexed herewith for your information and taking further necessary action, wherever required as per recommendations decided therein.

Yours faithfully,

(Dr. S. Eswara Reddy)
Drugs Controller General (India)

Encl. Copy of the minutes

Copy for information to:-

1. Directors of CDL/ CDTL/ RDTL of CDSCO
2. Zonal / Sub-zonal/ Port Offices of CDSCO
3. PPS to Secretary (Health)
4. PPS to Secretary (AYUSH)
5. PPS to DGHS
6. PPS to AS & DG (CGHS)
7. PPS to JS(R)
8. Chairperson, FSSAI, New Delhi
9. Chairman, NPPA, New Delhi
10. DG, NCB, New Delhi

MINUTES OF 55TH MEETING OF DRUGS CONSULTATIVE COMMITTEE HELD ON 31ST JANUARY & 01ST FEBRUARY, 2019 AT NEW DELHI

Inaugural Deliberations

Dr. S. Eswara Reddy, Drugs Controller General (India), Chairman, Drugs Consultative Committee (DCC), welcomed the participants and thanked them for sparing time for the meeting organised for achieving the goal of ensuring comprehensive and integrated system for uniform implementation of provisions of the Drugs and Cosmetics Act,1940 and Rules made thereunder.

The Chairman also welcomed Ms. Rita Teaotia, Chairperson, FSSAI for taking out time from her busy schedule to share her thoughts with the members. He mentioned that some products which were initially licensed as drugs are now being manufactured and marketed under food licence. He stated that the issue regarding amendment in the Schedule V which prescribes the limits of vitamins for prophylactic and therapeutic purposes was deliberated in the DTAB and as per recommendation of the Board, ICMR have been requested to give their recommendation in the matter. We are waiting for the response from the ICMR for taking further action in this regard.

He then requested the chairperson FSSAI to enlighten and advice the remedial measures that could be taken to address the issues.

Chairperson, FSSAI in her address stated that the DCC is an important platform for deliberation on various regulatory issues on both drugs and foods at national level. She mentioned that we should look human health as single point with no question on territory or domain. She appreciated that the agenda items identified for deliberation had strong significance in regulatory activities. As regards the issue of licensing of the border line products under drugs and foods, she mentioned that when FSSAI Act was drafted clear demarcation was provided between drugs and foods. As ICMR has already recommended for RDA and dose of vitamins, they should give their recommendations at the earliest for necessary amendment in Schedule V of Drugs and Cosmetics Rules.

She then highlighted the concerns regarding antimicrobial resistance and stated that recently, in one survey, various food products from animal origin were tested and it was found that 25% of the samples were having antibiotic residues. She requested the members to deliberate on this serious issue and come out with measures for preventing the misuse of antibiotics as there are no provisions to regulate animal feeds at present. Various antibiotics find their way back into the human food chain which in turn develop resistance to such antibiotics. She stressed that WHO list of antibiotics restricted for animal use should be followed and there should be proper regulation of animal feeds. She also stressed on the measures required to be taken to prevent off label use of antibiotics in animals. She expressed that it is our combined responsibility to institute a mechanism and work collaboratively for control on misuse of antibiotics to prevent antimicrobial resistance.

The DCG(I) while appreciating the thoughts of the chairperson FSSAI, apprised that DTAB in its 81st meeting held on 29.11.2018 has already recommended for prohibition for manufacture and sale of Colistin for use in food producing animals and animal feeds.

In the post lunch session on 1st day of the meeting Mrs. Ritu Dhillon, Member Secretary NPPA joined the meeting. The Chairman welcomed Mrs. Ritu Dhillon and thanked her for taking out her time to attend the meeting.

The Member Secretary NPPA greeted the members and stated that she had regular interactions with the State Drug Controllers on various issues relating to price control of drugs. She made a detailed presentation highlighting the details of number of drug formulations under Schedule I as well as new drugs under DPCO for which prices have been fixed and various initiatives taken by NPPA for effective price regulation in the country. She requested the members to work out a facilitation mechanism for collection of data from the manufacturers. She apprised that, NPPA is in process to set up Price Monitoring Research Units (PMRUs) under the scheme of 'Consumer Awareness, Publicity and Price Monitoring' of NPPA and requested the members to take quick initiatives to establish such units in their respective States.

She appreciated that most of the cases of violations of DPCO are initiated by drug control authorities and many of the States are very active in sending information on regular basis to NPPA. She stressed upon the need of creating a mechanism where interface will become more regular for effective price regulation of drugs in the country.

The issues regarding online system of licensing of manufacturing and sale of drugs were taken up for discussion. Shri R. Chandrashekar, DDC(I), CDSCO and CDAC made detailed presentations on the E-Governance initiatives of the CDSCO including the SUGAM Labs which has been developed recently for the drug testing laboratories. He stated that the SUGAM Labs software application can be extended to all the State Drug Testing Laboratories with the approval of the competent authority and urged all the States to utilise this facility. He also presented the salient features of the proposed Sales and Manufacturing Licenses Software Management System for all the States in the country. The salient features include online system for licensing of sales and manufacturing premises, post approval changes, issue of certificates and NOC's, monitoring of Not of Standard Quality drugs, enforcement activities, MIS reporting and analytical platform and software administration module. He requested the cooperation of the States/ UTs during the development of the software and further requested to designate one nodal officer from each State, furnish details of the preparedness w.r.t to IT infrastructure, prepare common checklists of documents and suggest suitable name/ logo for the portal.

DCG(I) then made a written request on 01.02.2019 to all State/ UT Drugs Controllers to make necessary arrangements for providing the necessary IT infrastructure so that the software can be deployed immediately as and when ready.

As invited, Secretary, Additional Secretary and Joint Secretary were present in the second day of the DCC meeting i.e., 01.02.2019. DCG(I) thanked them for sparing their

valuable time to attend the meeting and also greeted all the members for attending the second day of the meeting.

DCG(I) apprised about the deliberations held on first day which included CDAC presentation about the IT enabled centralized platform for uploading the manufacturing and sale license data to maintain the integrity of such data throughout the country. He also appreciated the members for their intervention in making the suitable check list for developing the centralized common online platform.

He mentioned about the initiatives taken by CDSCO like Capacity Building, proposed finalization of Clinical Trial Rules, draft Schedule M Rules, draft rules on online sale of medicines through E-pharmacy, separate rules for regulation of Cosmetics as a part of strengthening the drug regulatory system etc. He observed that keeping in view the roadmap to becoming the stringent regulatory system in the world, CDSCO is also taking the steps towards the PIC/S membership.

DCG(I) urged the guidance from the Secretary, MoHFW for forming an Independent Expert Committee for assessing the regulatory systems in CDSCO with a view to improve the transparency, accountability and efficiency in the system. He also pointed out the issue of making medicines by combining the allopathic drugs with ayurvedic drugs which are being sold in the name of AYUSH brand.

Thereafter, DCG(I) requested Joint Secretary to share his thoughts. Dr. Mandeep K. Bhandari, JS(R) greeted the members and stressed upon the necessity of ensuring quality, safety and efficacy of medicines for the consumers through robust regulatory system. He reminded that the India is the largest generic exporting country and the volumes are going to increase in the coming years.

He also requested State representatives to insist their State Governments to submit proposals and sign MOUs with Central Government at the earliest under the scheme for “Strengthening the State Regulatory System” including laboratories enabling timely allocation of funds.

Thereafter, Shri. Arun Singhal, Additional Secretary addressed the members. He pointed towards the responsibility of bringing quality in generic medicines for which the manufacturers are required to submit the bioequivalence data and stability data mandatorily with a view to build the confidence amongst the doctors and consumers. He suggested to conduct media campaign about necessity of generating stability and bio-equivalence studies data with a view to improve trust on generic medicines.

He stated that in order to increase the credibility of regulatory system and to earn respect, regulators should function in fair and transparent manner with a view to enhance their organization culture and may opt ombudsman system.

He also sought suggestions from the State Drug Controllers about the substitution of medicines by the pharmacists at the retail level. He pointed out the issue of multiple formulations having the same brand name. He also mentioned that in light of increasing number of notified medical devices being brought under regulations, the State Drugs

Controllers need to strengthen their system in terms of manpower and infrastructure reflecting their capability for regulation of devices.

The Additional Secretary also requested all State Drugs Controllers to create the awareness amongst the manufacturers about the importance of conducting the bioequivalence studies and stability studies.

DCG(I) pointed out the challenges in the States in implementing the mandatory provisions for submitting the bioequivalence data and stability data while applying for manufacturing license. Therefore, DCG(I) reiterated the need for the State Governments to be sensitized about effective implementation of the mandatory requirements to ensure quality of generic drugs. Thereafter, DCG(I) requested the Secretary to address the gathering.

Ms. Preeti Sudan, Secretary, MoHFW while welcoming all the members, stated that health of the community is one of the prime requirements to be taken care of. She requested the members to conduct inspections with utmost diligence. She suggested that the inspections should be categorized based on the nature and criticality and separate check lists for such category of inspections should be prepared.

She stressed that Government has increased focus on medical devices regulation and also suggested that a road map to bring all medical devices into regulation needs to be developed. She also pointed that there is large unregulated medical devices sector which needs to be addressed. She also stressed on training to increase the knowledge and skill on medical device regulations and suggested to consult the stake holders for effective implementation of amendments in Medical Device Rules, 2017.

She also pointed out that government is working towards upgrading GMP of Indian industry meant for the domestic supply to the level of WHO-GMP with a view to ensuring high standards of quality of drugs.

She also requested the members to review the faulty hip implant applications as the State Drugs Controllers are the Member Secretaries of the State Level Committees. She also requested all Drugs Controllers to bring awareness to the affected people regarding the compensation by wide publicity through local FM radio/ TV and other media.

She also stressed the members for the proper enforcement on recently banned Fixed Dose Combinations and to guard against issuance of licenses by State Drug Controllers without requisite processes being complied with under the Drugs and Cosmetics Act and Rules made thereunder. She also pointed out the necessity of provisions for marketing agencies to be also responsible for the quality of drugs marketed by them in the country.

While deliberating the issues on Oxytocin she pointed that strict enforcement of the Oxytocin should be carried out by conducting frequent raids to curb the illegal manufacturing, sale and distribution of Oxytocin.

DCG(I) mentioned that there is a necessity of promoting clusters which will facilitate the formulation development, stability testing and bioequivalence studies of drugs. State

Drug Controller, Haryana informed that Government of Haryana has already established such type of clusters and requested other states to initiate the process of developing such cluster by sensitizing their respective governments for ensuring quality of drugs.

DCG(I) thanked the Secretary for her valuable time and advice during the opening session.

Thereafter, DCC deliberated the agenda items one by one. The details of agenda and recommendations are as under:

AGENDA NO. 1

CONSIDERATION FOR APPROVAL OF REPORT OF 54TH DCC MEETING HELD ON 30.07.2018 AND ACTION TAKEN IN THE MATTERS ARISING OUT OF THE MEETING

DCG (I) briefed the Action Taken Report of the 54th meeting of DCC point wise and the same was approved by the members.

STATE AGENDA

AGENDA NO. 2

CONSIDERATION OF THE PROPOSALS FROM GOVT OF NCT OF DELHI

(i) The DCC was apprised that in the Medical Devices Rules, 2017 the licences issued in Form MD-5 or Form MD-6 for manufacturing of Class A or Class B Medical Devices does not have the provision for details of the competent technical staff responsible for the manufacture and testing of Medical Devices and proposed to incorporate the said provisions in licences.

DCC deliberated the proposal and agreed to incorporate the provision about details of the competent technical staff responsible for the manufacture and testing of Medical Devices in Form MD-5 or Form MD-6 in the MDR-2017. It was also recommended to include appropriate menu in SUGAM for the name of competent technical staff to identify the persons to ensure compliance with the provisions of the Rules.

(ii) The proposal was to incorporate the following sub-section, after sub section (2) in Section 36-AB of the Drugs and Cosmetics Act, 1940 pertains to Special Courts:

> '(3) a Special Court may, upon perusal of police report of the facts constituting an offence under this Act and/ or upon complaint made under above sections by an officer/ person authorized under Section 32 of the Act, take cognizance of that offence without the accused being committed to it for trial.'

DCC deliberated the proposal and opined that it is related to amendment in the Drugs and Cosmetics Act and the issue should be forwarded to the Ministry of Health and Family Welfare for consideration of the matter during amendment of the Act.

(iii) The proposal was to incorporate the following clause in definition of Spurious Drugs under Section 17B of the Drugs and Cosmetics Act, 1940:

'If it does not contain any amount of any of the active ingredient'.

DCC deliberated the proposal and opined that it is related to amendment in the Drugs and Cosmetics Act and the issue should be forwarded to the Ministry of Health and Family Welfare for consideration of the matter during amendment of the Act.

(iv) DCC appraised that, in draft rules published on e-pharmacies, it has been proposed to incorporate provision that such pharmacies should obtain drug licence and should be liable for all penal actions, which are applicable to brick & mortar pharmacies.

DCC deliberated the proposal and opined that the same issue is already under consideration for finalization of draft rules on e-pharmacy.

(v) Filing of F.I.R.by Drugs Inspector:

Allahabad High Court in Aug 2018 had given judgement that Drugs and Cosmetics Act is a special Act. Under the Act the Drugs Inspector doesn't have a power under CrPC to complain to the police. If drug inspector wants to arrest accused or file F.I.R he should take permission from the court. In view of this suggestions on the said judgement was requested.

During the deliberation, it was apprised that the Govt. is of the opinion to challenge the judgement by submitting SLP to the Hon'ble Supreme Court as the State Government has not yet challenged the judgement of the High Court. DCC agreed with the opinion of the Government.

AGENDA NO. 3

CONSIDERATION OF THE PROPOSALS FROM STATE OF GOA

The DCC opined that the issues raised in the agenda can be addressed through administrative process.

AGENDA NO. 4

CONSIDERATION OF THE PROPOSALS FROM STATE OF MAHARASHTRA

(i) In cosmetics products the percentage of ingredient should be mentioned on label in case of restrictions impose by BIS or under Drugs and Cosmetics Act 1940 and Rules under 1945

DCC was apprised that at present there is provision to mention the list of ingredient used in the cosmetics in the descending order of their content but the percentage of ingredient is not mandatory. Under BIS 4707 Part ll certain ingredient are allowed to be a part of cosmetics but restrictions of their percentages and restrictions to be used for particular class of cosmetics is mentioned. In order to keep a vigilant check on the available cosmetic in markets. It is suggested that if the provision of mentioning the percentage of restricted ingredient on label, it will be easy for the field officer to detect either by sampling or from label weather the cosmetics contents the restricted ingredient in restricted quantity or not for further action.

DCC deliberated the proposal and did not feel it necessary for the proposed provisions as the composition of ingredients are reviewed as per prescribed standards while granting the manufacturing license.

(ii) Uniformity in granting licence for cosmetic products all over the country.

At present there is no specific provision under the Drugs and Cosmetics Act or no guideline regarding the approval of cosmetics product by licensing authority.

Hence in certain State the product permission is given only on the name of product (the detail composition is not approved on the approval issued to manufacturer). During investigation of complaint or sample analysis certain ingredient are detected in cosmetics products which must not be a part of cosmetics like Phenol, Trichloro Acetic Acid etc. And during enquiry manufacturer state that they have submitted the composition to licensing authority while getting product permission, but on approval submitted by manufacturer only name of cosmetics is mentioned without any composition, in such situation investigation officer is under dilemma for taking proper action.

It was suggested that the complete composition of cosmetics product shall be mentioned in the approval issued by the licensing authority in the country in following format for uniformity throughout the country.

S.No.	Name of ingredient	Specification of ingredient	Percentage of ingredient	Purpose or function of ingredient

Small range of percentage for ingredient may be permitted to set the specification of product manufactured. At present in Maharashtra above format of approval of cosmetics is in practice.

While deliberating the proposal it was informed that finalization of Cosmetics rules is under consideration and DCC recommended that the matter may be consider while finalizing the rules.

(iii) Name of competent person in the format of Form 25, Form 26 and Form 28 to be incorporated.

DCC was apprised that at present the provision for mentioning the name of competent technical staff is in the format of Form 25, Form 26 and Form 28 and Competent Technical Staff is mentioned in rule 71 and rule 76. But as on today no provision in licence format for mentioning the name of competent person under whose supervision the sale shall be effected. This happens as there is no rule to mention name of competent person. It was requested that to incorporate the provision for mentioning the name of competent person in Form 25, Form 26 and Form 28.

DCC after deliberation deferred the proposal.

(iv) DCC was requested that manufacturers of Homoeopathic Medicines may be authorised to sale their product without getting separate licence in Form 20C or 20D by incorporating the word "The licence authorises the sale by way of wholesale dealing and storage for sale by the licensee of the drugs manufactured under the licensed subject to the condition applicable to licence for sale" in Form 25C and delete the word ‘who hold a licence in Form 20C’ from the format of Form 25C.

DCC was apprised that in Form 25 and Form 28 it is mentioned that "*The licence authorises the sale by way of wholesale dealing and storage for sale by the licensee of the drugs manufactured under the licensed subject to the condition applicable to licence for sale*". However such provision is not provided at present for manufacturer of Homoeopathic medicines i.e. licence holder in Form 25C and a separate licence in Form 20C is required to get the licence in Form 25C.

It was proposed that the provision for authorising the sale of Homoeopathic medicine by manufacturer without having independent licence in Form 20C may be made by incorporating the provision in Form 25C.

DCC, after deliberation did not feel it necessary to incorporate such provisions in the rules at present.

(v) Provision for mentioning the name of competent person-in-charge in Form 20D shall be made.

DCC was apprised that at present there is a provision in Form 20E i.e. Certificate of Renewal of Licence issued in Form 20D/ Form 20C for sale of Homoeopathic medicines to mention the name of competent person-in-charge but no such provision is there in Form 20D, the licence to sale of Homoeopathic medicines. In view of it the provision for mentioning the name of competent person-in-charge should be incorporated in Form 20D.

DCC, after detailed deliberation, recommended for incorporating the provisions about requirement of mentioning the name of competent person-in-charge in Form 20D as it was mentioned in the Form 20C.

(vi) To Authorise Licensing Authority for Sale licenses to issue stop sale order.

DCC was apprised that, as per Rule 85(2) the Licensing Authority for manufacturing are empowered to stop manufacturing, sale or distribution of the drug if in his opinion the licensee has failed to comply with any of the condition of the licence or with any provisions of the Act or rules made thereunder.

It was proposed that similar provision shall be made for Licensing Authority for sale by amending Rule 66 in the following manner.

DCC deliberated the proposal and recommended for incorporating a provision under Rule 66 providing that the Licensing Authority may direct the licensee to stop sale or distribution of the drugs, if, in his opinion, the licensee has failed to comply with any of the conditions of the licence or any provisions of the Act or Rules made thereunder.

(vii) Provision to be made to incorporate Section 33-EEB and EEC in Form 15

DCC was requested to consider proposal to make provision for prohibition of Ayurvedic, Siddha and Unani Drugs be made by making amendment in Form 15 as follows.

"Whereas, I have reason to believe that the stocks of drugs/ cosmetics/ Ayurvedic, Siddha and Unani Drugs in your possession detailed below contravene the provision of Section 18/ 33-EEB and/ or 33-EEC of the Drugs and cosmetics Act 1940".

DCC deliberated the proposal and recommended to refer the matter to AYUSH Drugs Consultative Committee for consideration.

(viii) Provision for mentioning the name and qualification of CTS in form MD5 and MD6.

The proposal was already discussed under Agenda No. 2(i)

(ix) Provision for approval of FDC/ P&P product of Homoeopathy Medicines.

DCC was apprised that, at present there is no clarity regarding the authority for approval of FDC/ P&P product of Homoeopathy Medicines, hence manufacturers are facing problem for the product for its approval. The issue should be considered.

DCC deliberated the proposal and recommended to refer the matter to AYUSH Drugs Consultative Committee for further consideration.

(x) Clear guideline for veterinary FDC products shall be issued.

DCC was apprised that, in the year 2013, DCG (I) had issued a circular regarding exemption of Veterinary FDC, however now we are receiving instructions from CDSCO that no FDC shall be granted without NOC of CDSCO. In view of it there is need of Clear guideline for veterinary FDC products from CDSCO.

DCC deliberated the issue and considered that new veterinary drug including FDCs required permission under Rule 122A or Rule 122B or Rule 122D, as the case may be. However CDSCO is also in process of making separate comprehensive rules for regulation of veterinary drugs including new veterinary drugs.

(xi) Notification of laboratory for testing the samples of Ayurvedic drugs which are declared as spurious due to presence of allopathic ingredient/s.

DCC was apprised that, if in Ayurvedic product Allopathic ingredient is found, then it is reported as spurious. If such report are challenged then, to whom sample is to be send through court is now questionable. If sample is send to CDL, they says it is Ayurvedic product and if send to Ghaziabad they says this lab is not authorized to test Allopathic ingredient/s, in such cases benefit is given to accused and it became difficult to bring the overall control on Spurious/ NSQ Ayurvedic drugs.

In view of it laboratory for testing the sample of Ayurvedic drugs which are declared as spurious due to presence of allopathic ingredient/s need to be notified.

DCC deliberated the matter and opined that in such case action can be taken under the provisions of the Drugs and Cosmetics Act both under the 'drug' as well as 'AYUSH' drug.

AGENDA NO. 5

CONSIDERATION OF THE PROPOSALS FROM STATE OF PUNJAB

(i) Accountability regarding manufacturing/ Sale/ distribution of alleged to be habit forming drugs.

Such circumstances may result in manufacture & availability of quality compromised products & further breeding to malpractices as the doctors & chemists are indulging in unethical medical practices, due to profession inter changeability.

DCC deliberated the issue and considered it as a serious issue and recommended that strict enforcement activities should be adopted to prevent such non-compliance of provisions of Drugs and Cosmetics Act, 1940 and Rules, made thereunder.

(ii) Uniform implementation of instructions of Drugs Controller General India, New Delhi issued vide letter dated 8-12-2018 &12-12-2018.

DCC apprised that, the Drugs Controller General India, New Delhi has issued 02 letters regarding grant of permission to manufacturing drugs formulations. The letter No. 244/2018-D dated 8-12-2018 & 4/01/2013-DC (Misc 13-PSC) (Pt.11) dated 12-12-2018, wherein the requirement of stability data to be submitted by the applicant manufacturer is for 6 months for the existing products & 03 months for products declared as rational by Kokate Committee respectively. The disparity between the periods mentioned in the letters has created a confusion among the regulators as well as the manufacturers regarding their justification, that why both are not at par with each other. Further, certain difficulties have been foreseen in the implementation of the instructions of these 02 above said letters, whether the State Licensing Authorities, shall consider the data generated by the applicant manufacturer under the licence in Form-29 or data generated by the manufacturer in the FRD / F&D and so on, or the State Licensing Authorities should wait for the guidelines, which are under framing by the sub-committee for implementation of these instructions & till then the instructions may be deferred.

DCC after detailed deliberation opined that necessary clarification may be issued in this regard after thorough examination of the matter.

(iii) Provisions for making API Manufacturers, accountable & responsible for quality & purity in case any drug product found out of specification.

It has been observed that in certain cases, API supplied by the various vendors are found not as per defined specifications with respect to their quality, specifications and purity and in certain cases the desired effects are not obtained i.e. the drugs are poorly bio-active/ bio-available, it is suspected that either such API's are not manufactured at the right premises or such API's are not manufactured with the required scientific techniques to produce the bio-active substance.

DCC, considering it as a serious matter, recommended that the State Drug Controllers should take action as per Drugs and Cosmetics Act, 1940 and Rules made there under. DCC also recommended for drawing of such samples as much as possible and get them tested to ensure the quality of APIs.

AGENDA NO. 6

CONSIDERATION OF THE PROPOSALS FROM STATE OF TEALANGANA

(i) The DCG(I) drug approval database i.e. Drugs@CDSCO available on CDSCO portal has to be made comprehensive.

a) DCC was apprised that, FDC list published till 20th December, 2018 indicates that the combination "Aceclofenac 100mg+Paracetamol 500mg tablets" as approved on 08.07.2004. But the DCG(I) Circulars dated: 23.09.2011 and 04.04.2012 regarding limiting of Paracetamol in Prescription Combination Products i.e. lowering of contents to 325 mg is not reflected on Drugs@CDSCO.

DCC after deliberation suggested to update the information about the approved drugs wherever it is applicable.

b) DCC was apprised that, Certain drug approvals indicated on the earlier portal www.cdsco.nic.in are not being reflected

DCC deliberated the issue and recommended for updating the data in the SUGAM online portal as well as CDSCO website.

c) DCC was apprised that, Certain drugs which are indicated in National List of Essential Medicines (NLEM) are not indicated in DCG(I) approved list

- Sucralfate Oral Liquid 1 gram
- 6-Mercaptopurine Tablet 50mg

DCC deliberated the issue and recommended to update the discrepancies, if any, in respect of such data.

(ii) DCC was apprised that, as the manufacturer would be complying with the importing country regulatory requirements, it is proposed to ***waive*** of bioavailability and bio-equivalence studies of Oral Solid Dosage Forms for BCS Class II & IV drugs for grant of licence for drug products meant for "*Export*" purpose only.

DCC after detailed deliberation did not agree to the proposal to grant such exemptions of bioavailability and bio-equivalence studies.

(iii) Clarification on Grant of Test Licence in Form 29 to a firm on the premises of a different firm (i.e. contractual research and development activities) and the criteria for grant of such test licences.

DCC deliberated the matter and clarified that License in Form-29 may be issued to the each site involved in the development of the drug.

(iv) Consideration of preparation of a guidance document regarding Approval of Veterinary Products detailing the basis of approval:

Presently there is no specific list of veterinary drugs approved by DCG(I), for the State Licensing Authority to verify before a license is granted to a veterinary drug. The list of Fixed Dose combinations approved by DCG(I) since 1961 till 20th December 2018, published on cdsco.gov.in portal and list of New Drugs Approved by CDSCO published on cdscoonline.gov.in portal contains only few veterinary products approved by DCG(I), as opposed to numerous veterinary drugs circulating in the market.

DCC recommended for updating the list. However, it was also informed that CDSCO is in process of framing separate rules for veterinary Drugs.

(v) Consideration of issuance of NOCs for grant of test licence in Form 29 by State Licensing Authorities on amending Rule 89 of Drugs & Cosmetics Rules, 1945:

Issuance of NOCs for Specific Quantity Exports has been delegated to State Licensing Authorities with effect from 20th August, 2018 and the NOCs and respective product approvals are being issued by the State Licensing Authorities.

Issuance of NOCs for grant of test licence in Form 29 may also be delegated to the State Licensing Authorities on amending Rule 89 of Drugs & Cosmetics Rules, 1945.

DCC deliberated the matter and did not agree to the proposal at present.

(vi) Amendment of Rule 49-A – Qualifications of a Licensing Authority:

DCC apprised, the clause (ii) of Rule 49-A which reads as “he has experience in the manufacture or testing of drugs or enforcement of the provisions of the Act for a minimum period of five years” may be amended as “he has experience in the enforcement of the provisions of the Act for a minimum period of five years”; as there is no direct recruitment for the post of licensing authority. The words “manufacturing or testing of drugs” may be omitted.

DCC was informed that the similar issue was already deliberated in earlier DCC meeting. Keeping in view the earlier deliberation, the committee felt that the existing qualification criteria for Licensing Authority may remain as such.

CENTRAL AGENDA

AGENDA NO. 7

CONSIDERATION OF THE RECOMMENDATIONS OF SUB-COMMITTEE FOR CREATION OF CADRE BASED (UNIFORM CADRES) POSTS IN ALL CENTRAL & STATE DRUGS TESTING LABORATORIES & SETTING UP OF MOBILE DRUGS TESTING LABORATORIES

Drugs Consultative Committee (DCC) in its 52nd meeting held on 18.09.2017 constituted a sub-committee under the chairmanship of Dr. Ravi Shankar IPS, Director General, DCA, Andhra Pradesh to make a proposal for cadre based posts for all the drugs testing laboratories and provision of one mobile testing laboratory for offices of CDSCO and each State/ UT under the Central Govt. Scheme.

The sub-committee examined the matter and submitted following recommendations for creation of cadre based (uniform cadres) posts in all Central & State Drugs Testing Laboratories & setting up of Mobile Drugs Testing Laboratories:

Dr. K. Bangarurajan, JDC(I), Convener of the subcommittee made a detailed presentation. The salient features are as under:

1. The following seven (7) cadres may be proposed across all the drugs testing labs in the country for uniform designations viz, Scientific Assistant, Senior Scientific Assistant, Junior Scientific Officer, Scientific Officer, Senior Scientific Officer, Deputy Director and Director. Further, the Departmental Promotion Sub-committee for the promotion to higher level posts at central level may be constituted by DoPT and at State level state sub-committee may be constituted by respective states.

2. Mobile Drugs Testing Laboratory to be sanctioned one to each district in the country with required manpower and infrastructure and one each to CDSCO zonal and sub-zonal offices for spot testing of drug samples.

3. To set-up a Central Portal for the generation of digitally signed analytical reports which would also make the national repository of all the NSQs and Standard Quality samples feasible.

DCC agreed to the recommendations of the sub-committee. However CSDCO proposed following six cadres in Central Drugs Testing Laboratories and forwarded to the Ministry for consideration:

S. No.	Designation of the post
1.	Director
2.	Deputy Director
3.	Senior Scientific Officer, Grade I
4.	Senior Scientific Officer, Grade II
5.	Junior Scientific Officer
6.	Scientific Assistant

AGENDA NO. 8

CONSIDERATION OF THE REPORT SUBMITTED BY SUB-COMMITTEE OF DRUGS CONSULTATIVE COMMITTEE (DCC) ON OVER-THE-COUNTER (OTC) DRUGS

DCC was apprised that a sub-committee was constituted in 52nd meeting held on 18.09.2017 under the chairmanship of Dr. Ravi Shankar IPS, Director General, DCA, Andhra Pradesh to examine comprehensively the drugs marketed in country vis-à-vis conditions for sale stipulated under various schedules, namely H, H1, G, X, K and recommend the list of drugs which may be considered for marketing as OTC along with conditions to be followed.

The sub-committee examined the matter in detail and submitted its report. The sub-committee has given recommendations on the following aspects on OTC drugs.

1. Definition of OTC drug
2. Basic Characteristics of OTC drugs
3. Classification of OTC drugs
4. Preparation of Initial list of OTC Drugs
5. Regulation of Rx Drug to OTC Drug Switch Process
6. Regulation of new OTC drug approval
7. Manufacturing and labelling of OTC drugs
8. Distribution and sale of OTC drugs
9. Advertisement of OTC drugs
10. Pricing
11. Miscellaneous

DCC opined that detailed examination of the report submitted by subcommittee is required to take further action in this regard. Therefore, DCC constituted a subcommittee under chairmanship of Shri. N.K. Ahooja, Drugs Controller, Haryana to examine the report on Over-The-Counter (OTC) drugs.

Composition of sub-committee:

1. *Shri. N.K. Ahooja, Drugs Controller, Haryana* — *(Chairman)*
2. *Shri. AmareshTumbagi, Drugs Controller, Karnataka* — *(Member)*
3. Shri. Tajber Singh, *Drugs Controller, Uttarakhand* — (Member)
4. Shri. Amit Duggal, *Senior Drugs Inspector,* *Drugs* Control Dept., Chandigarh — (Member)
5. *Shri. R. Chandrashekhar, DDC(I),CDSCO (HQ)* — *(Convener)*

The sub-committee shall examine the report and submit their recommendations to DCC for further consideration.

AGENDA No. 9

CONSIDERATION OF THE REPORT SUBMITTED BY SUB-COMMITTEEFOR REVISION OF THE FEES FOR THE TEST OR ANALYSIS BY AMENDING SCHEDULE B AND SCHEDULE B-1 OF THE DRUGS AND COSMETICS RULES, 1945

DCC was apprised that, in its 53rd meeting held on 09.04.2018 constituted a sub-committee under the chairmanship of Dr. N. Murugesan, Director, CDTL, Chennai, for amending Schedule B and Schedule B-1 of Drugs and Cosmetics Rules, 1945 in respect of the proposed hike in fees for test or analysis of drugs.

Dr. N. Murugesan, Director, CDTL, Chennai, the chairman of the sub-committee made a detailed presentation in this regard. Major recommendations are as under:

1. Revision of fees for test or analysis by the Central Drugs Laboratories, Central and State Drugs Testing Laboratories under Schedule B of Drugs and Cosmetics Rules, 1945.
2. Revision of fees for the test or analysis by the Central Drugs Laboratory, Government Analyst of Central/ State Drugs Testing Laboratories under Schedule B1 of Drugs and Cosmetics Rules, 1945.
3. Inclusion of a separate schedule in the Medical Device Rules, 2017 for the test or analysis fees of notified medical devices.

DCC agreed to the recommendations of the sub-committee and recommended to initiate process for necessary amendment in the Rules.

AGENDA NO. 10

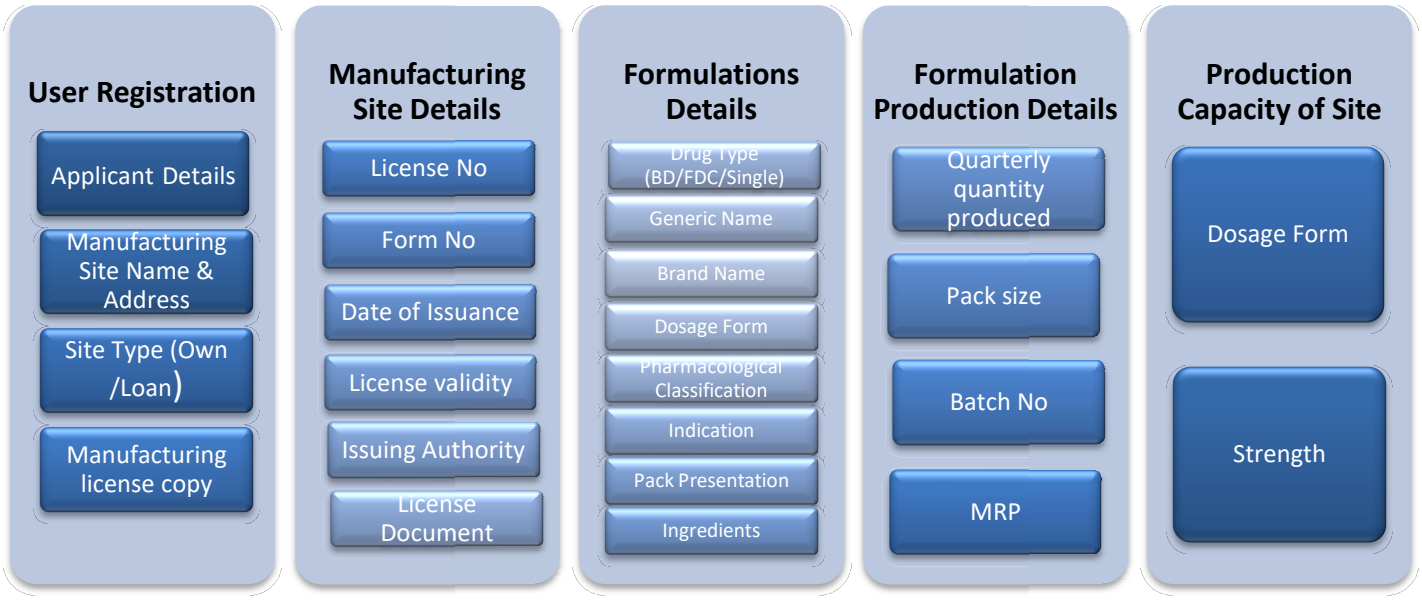
CONSIDERATION OF THE PROPOSAL FOR EFFECTIVE IMPLEMENTATION OF RULE 84AB REGARDING MANDATORY UPLOADING OF INFORMATION PERTAINING TO THE LICENSES GRANTED FOR MANUFACTURE FOR SALE OR DISTRIBUTION OF DRUGS IN ONLINE PORTAL SUGAM AS REQUIRED UNDER G.S.R.19(E) DATED 10.01.2019

DCC was apprised about the matter of updating the database of drug manufacturing facilities and approved drug formulations in India on SUGAM Portal. The matter was also deliberated in earlier DCC and DTAB.

The Central Government has amended the Drugs and Cosmetics Rules, 1945 vide notification G.S.R.19(E) dated 10.01.2019 making online submission of data through SUGAM portal as a mandatory requirement under the Rules.

As per the notification, the licencee shall register with portal SUGAM (www.cdscoonline.gov.in) and upload information, as per the format provided in the said portal which includes manufacturing site details (License no, Form no, date of issuance, License validity, etc.), formulation details (drug type, generic name, branded name if any, dosage form, pharmacological classification, indication, pack presentation, etc.), formulation production details (quarterly quantity produced, pack size, batch no, MRP, etc.) pertaining to the licences granted for manufacture for sale or distribution of drugs and the information so provided shall be updated from time to time and these information are required to be verified by the concerned State Licensing Authority for confirmation.

The format provided in the SUGAM portal for capturing data from the manufacturers is as under:



DCC deliberated the matter and recommended that all State Drug Controllers should ensure the effective implementation of Rule 84AB introduced vide G.S.R.19(E) dated 10.01.2019 as mentioned above at the earliest.

AGENDA NO. 11

CONSIDERATION OF THE PROPOSAL FOR A COMMON SOFTWARE PLATFORM FOR DRUG LICENCES MANAGEMENT FOR ALL THE STATES IN THE COUNTRY

DCC was apprised that, in the 53rd meeting, the Secretary, MoHFW highlighted the importance of having online submission and review of applications for grant of manufacturing and sale licences and comprehensive database. She further stated that this software may be used pan India, for uniform implementation.

After examining various systems that are being used in the country and the software applications developed by CDSCO in collaboration with CDAC, it was decided to develop a Drug Licence Management System for all the states in the country. In order to develop a software application meeting the needs of the country within minimum possible duration, CDAC is being entrusted. It is proposed to develop the software in seven modules, viz.

1. Online licensing system,
2. Process for amendment of licenses,
3. Process for issue of certificates and NOCs,
4. Process regarding Not of standard quality drugs,
5. Process for enforcement activities,
6. MIS reporting and analytical platform and
7. Software administration module.

The proposed software platform would enhance—

- Transparency by being able to track the status of the application
- Predictability by being able to see the time left for processing the application and prescribed timelines for disposal of each application
- Reducing interface with the applicant by way of online submission, online queries and digital approvals
- Payment of fee online through Bharatkosh or similar gateways
- Faster dissemination of information through integration with e-Sanchit etc.
- Integrating the Central (SUGAM) and State portals (proposed)

The proposed cost of the project is 274.9 lakhs. The software is proposed to be launched within 45 days from the date of initiation and the project will be completed within a year. The total duration of the project is 3 years including 2 years maintenance period.

Some states pointed out that development of new software is in the pipeline and therefore requested CDSCO to address a letter regarding the new and ongoing IT

software projects. DCG (I) has issued a letter in this regard and provided a copy to all State Licensing Authorities during DCC meeting.

DCC deliberated and recommended that:-

- *Each State/UT may designate one nodal officer for the purpose to furnish inputs and interact with IT cell at CDSCO, HQ.*
- *Each State/UT may furnish details of the preparedness w.r.t. IT infrastructure.*
- *To prepare common checklist of documents and suggest suitable name/logo for the portal.*

Preliminary work on common checklist was undertaken by small group during sidelines of the meeting and in addition to general information with respect to product, it was commonly proposed that following points also need to be included in the check list i.e.

a. *Report of stability studies of the product*
b. *Method of analysis & specifications*
c. *Analytical method validation (in case of non pharmacopoeial method)*
d. *Report of process validation*
e. *Bio availability report (for class II and class IV oral dosage forms) as per Drugs & Cosmetics Rules, 1945.*
f. *Copy of Form-29 (obtained for manufacturing and testing for data generation)*

AGENDA NO. 12

CONSIDERATION OF PROPOSAL FOR ONLINE PROCESSING AND ISSUANCE OF WHO-GMP CERTIFICATE OF PHARMACEUTICAL PRODUCTS AND ITEMS INCLUDED IN CLAA SCHEME

DCC was apprised that, presently submission and processing of various categories of applications including applications for import registration and licences at CDSCO are being done through SUGAM portal. Online submission and processing has also been developed for grant of approval to conduct bioequivalence studies for export purposes.

In order to improve the transparency and efficiency, online system for submission and processing of applications for grant of WHO-GMP Certificate of Pharmaceutical Products and items included in CLAA scheme is required to be developed by Central and State in coordination through online portal.

DCC deliberated and agreed to the proposal.

AGENDA NO. 13

CONSIDERATION OF THE PROPOSAL ON STATUS OF STATE LEVEL EXPERT COMMITTEES FOR PAYMENT OF COMPENSATION TO PATIENTS IMPLANTED WITH ASR HIP IMPLANT MANUFACTURED BY M/S DEPUY INTERNATIONAL LTD (JOHNSON AND JOHNSON)

DCC was apprised that, the Central Government has constituted Central Expert Committee and advised for State Level Committees to implement the recommendations of Dr. Aggarwal Committee. The Central Expert Committee was constituted under the chairmanship of Dr. R.K. Arya to determine the quantum of compensation. In this regard, all State and Union Territories were required to form State Level Committees vide order no. X.11035/25/2015-DFQC dated 30.08.2018 for assisting patients for the examination and evaluation of affected patients. It was also required that the report of the individual shall be submitted by the State Level Committees to the Central Expert Committee including its recommendations within a period of 60 days from the date of the receipt of the application from Central Expert Committee.

DCC requested the members to review the applications related to faulty hip implant received by them as the State Drugs Controllers are the Member Secretary of the State Level Committees. DCC also requested the members to bring awareness to the affected people through wide publicity.

AGENDA NO. 14

CONSIDERATION OF THE PROPOSAL FOR INCORPORATION OF QR CODING ON PRIMARY, SECONDARY AND TERTIARY LEVELS OF PACKING OF DRUGS FOR TRACKING AND TRACING OF DRUGS IN THE SUPPLY CHAIN

DCC was apprised that, Drugs Technical Advisory Board (DTAB) in its 69th meeting held on 22.04.2015 deliberated a proposal to make mandatory bar coding on primary, secondary and tertiary levels of packing of drugs for tracing the origin and movement of drugs from manufacturer to retail level through a system of networking. The system of bar coding was proposed to be introduced to ensure the authenticity of the drugs moving in the national trade. DTAB recommended that the Drugs and Cosmetics Rules, 1945 may be amended as proposed for the adoption of bar coding system.

Accordingly, Ministry had published draft rules vide G.S.R.449(E) dated 03.06.2015. However, large numbers of objections were received from the stakeholders raising concerns about implementation of the proposed rules and hence the draft rules have not yet been finalized.

Now it is proposed to incorporate QR code (Quick Response Code) which is a two-dimensional (2D) barcode that can store a lot of information and require smaller space compared to a traditional barcode, on primary, secondary and tertiary levels of packing of drugs for tracking and tracing the origin and movement of drugs from manufacturer to retail level through a system of networking.

DCC deliberated the matter and felt that, comments may be obtained from the stake holders for consideration before finalizing the mechanism of QR coding on the label of drugs.

AGENDA NO. 15

CONSIDERATION OF THE PROPOSAL TO DEVISE A MECHANISM UNDER THE DRUGS AND COSMETICS RULES, 1945 TO AVOID SAME TRADE NAME FOR DIFFERENT DRUGS

DCC was apprised that, earlier the matter was deliberated by DTAB in its 81st meeting held on 29.11.2018. The Board has recommended for devising a mechanism under the Drugs and Cosmetic Rules 1945 to include provisions for regulating the brand names/ trade names of Pharmaceutical products.

DCC after deliberation agreed to the proposal.

AGENDA NO. 16

CONSIDERATION OF THE PROPOSAL FOR CLARIFICATION ON EXEMPTION OF DETTOL ANTISEPTIC LIQUID (CLOROXYLENOL, TERPINEOL AND ALCOHOL) AS ANTISEPTIC AND DISINFECTANT IN INDIA UNDER SCHEDULE K (RULE 123) OF DRUGS AND COSMETICS RULES 1945

DCC was appraised that, under the Clause 12, Schedule K of the Drugs and Cosmetics Rules, 1945 it is provided that 'Substances intended to be used for destruction of vermin or insects, which cause disease in human beings or animals, viz. Insecticides and Disinfectants' are exempted from the provisions of Chapter IV of the Act and the Rules thereunder which require them to be covered by a sale licence.

Representation has been received from Reckitt Benckiser (India) Private Limited to issue a clarification that Dettol Antiseptic Liquid (Chloroxylenol, Terpineol& Absolute Alcohol Antiseptic Liquid) which is Antiseptic-Disinfectant does fall under Clause 12, Schedule K of Drugs and Cosmetics Rules 1945 and no sale licence would be applicable.

DCC recommended that the issue may be referred to the subcommittee constituted for examination of report on OTC drugs. DCC also recommended to consider other such products while examining the issue. The sub-committee should submit its report within three months.

AGENDA NO. 17

CONSIDERATION OF THE PROPOSAL FOR CREATION OF MONITORING CELLS IN ALL DISTRICT OF THE COUNTRY AS PER THE DIRECTION OF NATIONAL HUMAN RIGHTS COMMISSION (NHRC)

DCC was apprised that, in light of news item under caption “Antibiotics Sold in India Pose Global Superbug Threat” published in the Asian Age dated 06.02.2018, National Human Rights Commission (NHRC) had issued a notice on 12.02.2018 under case no 34/90/0/2018/UC and requested the Ministry of Health and Family Welfare (MoHFW) for submitting a detailed report on the matter.

Accordingly a detailed report was submitted by MoHFW to NHRC. After reviewing the detailed report, NHRC vide letter dated 25.04.2018 has directed to create monitoring cells in all the districts of the country to monitor the proper implementation of the directions given in this regard by the Central Government and other authorities so that prohibited drugs are not sold in the market.

In compliance with the directions of the NHRC, CDSCO vide letter F.No. DCGI Legal/Misc/08/2018-DC dated 10.07.2018, 08.11.2018 and 19.12.2018 has requested all the State/ UT Drug Controllers to create monitoring cells in all the districts.

Now, the NHRC vide letter dated 02.01.2019 has again directed to submit the updated report regarding creation of monitoring cells as directed by the commission.

DCC deliberated the matter and recommended that all State Drugs Controllers should create such monitoring cells at the earliest so that Action Taken Report could be submitted to NHRC.

AGENDA NO. 18

CONSIDERATION OF THE PROPOSAL TO CONSTITUTE INDEPENDENT EXPERT COMMITTEE TO AUDIT FUNCTIONING OF CENTRAL & STATE DRUG CONTROL AUTHORITIES

DCC was appraised that, in its 54th meeting held on 30.07.2018 deliberated the issues relating to quality monitoring of drugs and recommended for constitution of independent expert committee(s) to audit Central & State Drug Control Authorities including laboratories.

DCC deliberated for modalities to be developed for functioning of Independent Expert Committee and recommended that members should consider the proposal for auditing the regulatory authorities for strengthening the system. Such auditing may be initially started with assessment of CDSCO and then followed by State Drugs Control Authorities.

AGENDA NO. 19

CONSIDERATION OF THE PROPOSAL TO UPGRADE THE ALL STATE GOVERNMENT DRUGS TESTING LABORATORIES TO GET NABL ACCREDITATION

DCC was apprised that, National Accreditation Board for Testing and Calibration Laboratories (NABL) is an autonomous body under the aegis of Department of Science & Technology, Government of India. NABL has been established with the objective to provide Government, Industry and Society in general with a scheme for third-party assessment of the quality and technical competence of testing and calibration laboratories. Government of India has authorized NABL as the sole accreditation body for Testing and Calibration of laboratories. NABL has agreements with ILAC (International Laboratory Accreditation Conference) and APLAC (Asia Pacific Laboratory Accreditation Cooperation). These are especially valuable for international recognition and mutual acceptance of test results. The NABL undertakes the assessment and accreditation of Testing and Calibration Laboratories, in accordance with the international standard ISO/IEC 17025 and ISO 15189.

The benefits of NABL accreditation are as below:

- Increased confidence in Testing/ Calibration Reports issued by the laboratory.
- Better control of laboratory operations and feedback to laboratories as to whether they have sound Quality Assurance System and are technically competent.
- Savings in terms of time and money due to reduction or elimination of the need for re-testing of products.

Currently, there are seven Central Drugs Testing Laboratories and all are NABL accreditated. However, in case of State Drugs Testing Laboratories, only laboratories of Maharashtra, Gujarat and Kerala are NABL accreditated and laboratory of Karnataka is in the process of NABL accreditation. Remaining State Drugs Testing Laboratories are not NABL accreditated.

DCG (I) requested the members that in order to ensure quality and accuracy of testing, it is important to have Quality Management System in the laboratories and NABL accreditation. He also suggested members to take guidance from Central laboratories for the accreditation process.

DCC agreed to the proposal.

AGENDA NO. 20

CONSIDERATION OF THE PROPOSAL REGARDING RETENTION FEE CERTIFICATE/ LICENCE VALIDITY CERTIFICATE AS CONSEQUENT TO PERPETUITY OF LICENCES

DCC was apprised that the Drugs and Cosmetics rules, 1945 were amended vide G.S.R.1337(E) dated 27.10.2017 providing that the manufacturing and sale licences of drugs shall remain valid if licensee deposits licence fee every five years, unless the licences are suspended or cancelled by the Licensing Authority.

It was proposed for devising a mechanism for issue of retention fee certificate/ licence validity certificate in a common format uniformly throughout the country by all State Licensing Authorities by introducing a new form/ certificate as required.

DCC deliberated the matter by considering that issuing of the licence is becoming on line and opined that the matter may considered once the online system is established.

AGENDA NO. 21

CONSIDERATION OF THE PROPOSAL FOR RECONSTITUTION OF SUB-COMMITTEES CONSTITUTED EARLIER WHICH HAVE NOT DELIBERATED AND SUBMITTED THEIR REPORT ON THE RESPECTIVE SUBJECT

1. **Sub-committee to examine the issues of manufacturing of drugs on P to P basis and marketing of such product of a particular manufacturer under multiple brands by multiple firms.**

   DCC deliberated the matter and opined that there is no need to reconstitute the sub-committee in present context.

2. **Sub-committee to review the exemptions provided under Schedule K from taking sale licences by the RMPs for supplying medicines including Vaccines to their patients.**

   DCC deliberated the matter and recommended to reconstitute the sub-committee under chairmanship of Shri. Tajber Singh, Drugs Controller, Uttarakhand with following composition:

   Composition of sub-committee:

   1. *Shri.Tajber Singh, Drugs Controller, Uttarakhand* — *(Chairman)*
   2. *Smt. Mamina Patnaik, Drugs Controller (I/C), Orissa* — *(Member)*
   3. *Shri. Shobhit, Deputy Drugs Controller, M.P.* — *(Member)*

4. *Smt. A. Visala* *(Convener)*
   DDC(I), CDSCO, Hyderabad Zone

The sub-committee shall examine the issue and submit its report for upcoming DCC for consideration.

3. Sub- committee for Effective Recall system of Not of standard Quality (NSQ) drugs

DCC deliberated the matter and recommended to reconstitute the sub-committee under the chairmanship of Shri. K.V. Rajendranath Reddy, IPS, DG, DCA, Andhra Pradesh with following composition:

Composition of sub-committee:

1. *Shri. K.V. Rajendranath Reddy, IPS* *(Chairman)*
   Director General, DCA, AP
2. *Shri. Amit Duggal* *(Member)*
   Senior Drugs Inspector,
   Drugs Control Dept. Chandigarh
3. *Shri. Dinesh Kumar Tiwari,* *(Member)*
   Assistant Commissioner (Drug), U.P.
4. *Smt. Rubina Bose* *(Convener)*
   DDC(I), CDSCO, West Zone

The sub-committee shall examine the issue and submit its report for upcoming DCC for consideration.

4. Proposal to consider issues relating to the guidelines issued for taking action on samples of drugs declared spurious or not of standard quality in the light of enhanced penalties and to consider issues regarding lack of SOPs and uniformity in administration of the provisions of the Drugs and Cosmetics Act, 1940 and Rules, 1945.

DCC deliberated the matter and opined that there is no need to reconstitute the sub-committee in present context.

AGENDA NO. 22

CONSIDERATION OF THE PROPOSAL FOR EXTENSION OF PERIOD FOR NOT TO DISPOSE STOCK OF DRUGS OR COSMETICS SEIZED UNDER SECTION 22 (1) (c) OF THE DRUGS AND COSMETICS ACT, 1940

DCC was apprised that powers are provided under 22(1) (c) of the Drugs and Cosmetics Act, 1940 and Rule 54 & Rule 145C of the Drugs and Cosmetics Rules, 1945 that an Inspector can issue an order in Form 15 for not to dispose of the stocks of drugs/ cosmetics for a period of 20 days from the date of the order, if the inspector have reason to believe that the stocks of drugs/ cosmetics contravene the provisions of Section 18 of the said Act.

Keeping in view the time taken for forwarding the samples to Government Analyst by Inspector, time taken for testing/ analysis by the Government Analyst and forwarding the report back to the Inspector, the time period may be extended from a period of 20 days to a period of 40 days.

DCC after deliberation opined that extension of time period may not be required in most of the cases and hence the proposal may not be required at present.

AGENDA NO. 23

CONSIDERATION OF THE PROPOSAL TO AMEND THE DRUGS AND COSMETICS RULES, 1945 FOR USE OF SEPARATE COLOUR CODE AND SYMBOL FOR IDENTIFICATION OF GENERIC MEDICINES FROM OTHER MEDICINES

DCC was apprised that a matter has been raised under Rule 377 by a Hon'ble M.P. during Lok Sabha debates for differentiating the generic medicines from other branded medicines. He mentioned that Govt. is doing more efforts to provide generic medicines to the public and also public have shown trust in the generic medicines because of its low prices. But due to ignorance and unawareness of the public, traders are fudging the poor public because the government has not specified features to differentiate the generic medicines from other medicines.

Hence, the Hon'ble M.P has requested to use separate colour code and symbol for identification of generic medicines in the same manner as in the case of eatable items of vegetarian and non-vegetarian origin.

In this regard, it may be mentioned that DTAB in its 81st meeting held on 29.11.2018 while deliberating the proposal to explore the feasibility of providing a separate shelf/ rack for generic medicines in pharmacy recommended to include definition for Generic Medicine under Drugs and Cosmetic Rules, 1945.

DCC after deliberation felt that it is appropriate to seek views of all stake holders for consideration of the proposal. Therefore, a stakeholders meeting may be organized in this regard.

AGENDA NO. 24

CONSIDERATION OF THE PROPOSAL TO AMEND DRUGS AND COSMETICS RULES, 1945 TO MAKE RULES UNDER SECTION 32B OF THE DRUGS AND COSMETICS ACT, 1940 FOR COMPOUNDING OF CERTAIN OFFENCES

DCC was apprised that compounding of certain offences are specified under Section 32B of the Drugs and Cosmetics Act, 1940 that an offence punishable with imprisonment only, or with imprisonment and also with fine, may, either before or after the instructions of any prosecution, be compounded by the Central Government or by any State Government or any officer authorized in this behalf by Central Government or a State Government, on payment for credit to that Government of such sum as that Government may, by rules made in this behalf.

However, till date no such rules have been framed under this section.

DCC deliberated the matter and recommended to constitute a sub-committee under the Chairmanship of Dr. V.G. Somani, Joint Drugs Controller (India) with following composition.

Composition of sub-committee:

1. *Dr. V.G. Somani, JDC(I), CDSCO(HQ)* — *(Chairman)*
2. *Shri. Amrut Nikhade, JDC (HQ), FDA, Maharashtra* — *(Member)*
3. *Shri. Atul Kumar Nasa, Deputy Drugs Controller & Controlling Authority Delhi (NCT)* — *(Member)*
4. *Shri.AmareshTumbagi, Drugs Controller (A/C), Karnataka* — *(Member)*
5. *Smt. Ritu Sahay, Director (Drugs), Jharkhand* — *(Member)*

The sub-committee shall examine the issue and submit its report for consideration in the next DCC meeting.

AGENDA NO. 25

CONSIDERATION OF THE PROPOSAL TO AMEND THE DRUGS AND COSMETICS RULES, 1945 PERTAINING TO QUALIFICATION OF THE COMPETENT TECHNICAL STAFF FOR GRANT OF LICENSE FOR MANUFACTURING OF DRUGS

DCC was apprised that representation has been received from Pharmacy Council of India (PCI), New Delhi regarding amendment of the Drugs and Cosmetics Rules pertaining to qualification of the competent technical staff for grant of license for manufacturing of drugs.

Central Council of the PCI in its 104th meeting held in August, 2018 noted the following:

a. Advancement in the field of Pharmaceutical Sciences has led to many quality challenges.

b. Besides a graduate in Pharmacy, a graduate in Science or graduate in Chemical Engineering or Chemical Technology or Medicine is also defined as a competent technical staff for manufacturing of drugs.

c. Approximately one lakh B. Pharmacy graduates are passing out from various pharmacy institutions in the country and hence there is no dearth of B. Pharmacy graduates in the country.

Subsequently, Central Council of the PCI unanimously resolved to suitably amend the conditions for grant of licence for manufacturing of drugs to the effect that only graduate in Pharmacy shall be defined as a competent staff for manufacturing of drugs.

Accordingly, PCI has requested to amendment of the Drugs and Cosmetics Rules, 1945, providing that the qualification of competent technical staff to supervise the manufacturing of the drugs shall be a Graduate in Pharmacy/ Pharm.D from an institution approved by the Pharmacy Council of India under the Pharmacy Act 1948 (VIII of 1948).

DCC deliberated the matter and agreed for addition of Pharm.D as one of the qualification for competent technical staff to supervise the manufacturing of drugs to the existing qualifications by amending the Drugs and Cosmetics Rules, 1945 wherever applicable.

AGENDA NO. 26

CONSIDERATION OF THE PROPOSAL TO REPLACE THE WORDS "CHEMISTS AND DRUGGISTS" BY "PHARMACY" IN RULE 65(15)(b) OF THE DRUGS AND COSMETICS RULES, 1945

DCC was apprised that a representation has been received by Ministry of Health and Family Welfare from Karnataka State Registered Pharmacists Association (KSRPA), urging the Union government to remove the words "Chemists and Druggists" from Rule 65(15)(b) of the Drugs and Cosmetics Rules and replace it with "Pharmacy" in order to give trade of medicines a better professional recognition.

KSRPA has requested the government to amend the Rule 65(15)(b) and Rule 65(15)(c) so that medical shops may be called Pharmacy at the earliest as this is in concurrence with the international practice of calling a medical shop selling medicines by this name and also provide an identity and sense of value to the practising pharmacist at the outlets.

DCC deliberated the issue and recommended to replace the words "Chemists and Druggists" by "Pharmacy" in Rule 65(15)(b) of the Drugs and Cosmetics Rules, 1945.

ADDITIONAL AGENDA NO. S1

CONSIDERATION OF THE PROPOSALS FROM STATE OF MADHYA PRADESH

(i) Consideration of proposal to provide guidelines regarding provision of submitting fees for inspection by the Drugs Manufacturing Licensees in case of retention of licence.

DCC was apprised that, as per Gazette Notification of Govt. of India vide No. 1337(E) dated 27-10-2017, according to point No. 16; amendment made in Rule 72, point No. 19; amendment made in Rule 73AA, insertion of Rule 73AB, provision of renewal of Drugs Manufacturing Licences has been omitted and now licensee has to submit licence retention fee which shall be equivalent to respective fee required for the grant of such licence excluding inspection fees

Also in the said notification, according to point No. 19; insertion of 73AB(2) stating the provision of inspecting the licensed premises to verify the compliance with the conditions of licence and the provisions of the act and rules not less than once in three years or as needed as per risk based but provision of submitting fees for inspection by the licensee is not clear in the notification anywhere.

DCC deliberated the matter and recommended to follow the current procedure for depositing the licence retention fee.

(ii) Consideration of proposal to provide guidelines regarding testing/ verification of chemical/ reagents/ salts/ kits used in pathology laboratories.

DCC was apprised that as per reference No. 2 PIL 12/2015 Amitabh Gupta Vs Union of India & others has been filed in Hon'ble High Court, Jabalpur (M.P.), in which petitioner has raised the issue for ensuring proper testing/ verification of chemical/ reagents/ salts/ kits imported or manufactured in India to be used in pathology laboratories asking whether any standard or norms were framed or prescribed by IPC or not.

It is suggested that standards or norms have to be framed for testing and verification of chemical/ reagents/ salts/ kits used in pathology laboratory as these items can directly/ indirectly affect largely human health.

DCC deliberated the matter and opined that since there is large number of chemical/ reagents/ salts/ kits used in pathology laboratory, it is not possible to prepare standards for testing and verification of those materials used in pathology laboratory.

(iii) Consideration of proposal to provide guidelines regarding remaining 214 FDCs among 294 FDCs out of which 80 FDCs have been prohibited by Ministry of Health and Family Welfare, Govt. of India.

DCC was apprised that Ministry of Health and Family Welfare, Govt. of India has issued Gazette notifications S.O.180(E) to S.O.259(E) dated 11.01.2019 wherein 80 FDCs were prohibited after recommendation of DTAB sub-committee.

On the basis of recommendation of the Board, Central Government is satisfied that there is no therapeutic justification for these FDCs, hence, under section 26(A) of Drugs and Cosmetic Act, 1940 (23 of 1940), the Govt. has prohibited the manufacture for sale, sale and distribution of 80 FDCs in the public interest, with immediate effect.

DCC was informed that the matter is already under consideration by the C.K. Kokate committee. Therefore the matter may be considered further once Kokate committee report is available.

(iv) Consideration of proposal to address the issue of online sale of drugs.

DCC was apprised that, notably various applications and representations have been received in this Administration from Madhya Pradesh Chemists & Druggist Association against online sale of drugs enclosed with Hon'ble High Court of New Delhi order dated 12-12-2018 in W.P. (C)11711/2018 stating that respondents are injuncted from online sale of medicine without licence and respondents are directed to ensure that same is prohibited until further orders. Also Hon'ble High Court of Chennai order in W.P. No. 28716/2018 & WMP 33542/2018 dated 31-10-2018 stating grant interim injunction against the online sale of medicines without licence and Hon'ble High Court of Bombay order in PIL No. 170/ 2015stating to submit status report on action taken against persons/ entities involved in online sale of medicine by Govt. of Maharashtra through concerned department. It has been requested to this Administration to take all possible action against all online sales of medicine, activities carrying out by persons/ entities in the State of Madhya Pradesh.

DCC deliberated that the draft notification was issued to amend the Drugs and Cosmetics Rules, 1945 for incorporation of separate provisions for regulation of sale of drugs by e-pharmacy in the country. DCC however deliberated that till the publication of final notification, any violations regarding online sale of drugs shall be dealt as per the existing provisions under the Drugs and Cosmetics Act, 1940 and Rules thereunder.

ADDITIONAL AGENDA NO. S2

CONSIDERATION OF THE PROPOSALS FROM NATIONAL PHARMACEUTICAL PRICING AUTHORITY (NPPA) REGARDING DEVELOPMENT OF GREATER SYNERGY BETWEEN NPPA AND STATE DRUGS CONTROLLERS (SDCs)

(i) Setting up of Price Monitoring and Resource Units (PMRUs)

DCC was apprised that, NPPA is in proposes to set up PMRUs under the scheme of 'Consumer Awareness, Publicity and Price Monitoring' of NPPA. Briefed the functionalities of PMRUs as under:

a. The primary function of PMRUs will be to assist NPPA in Price Monitoring, Drug Availability and IEC. Total 21 States have given their consent for formation of PMRU. These are Assam, Gujarat, Haryana, Maharashtra, Manipur, Odisha, Punjab, Tripura, Mizoram, Rajasthan, Chhattisgarh, Bihar, Nagaland, Goa, Delhi, Tamil Nadu, Madhya Pradesh, Uttarakhand, Puducherry, Andhra Pradesh and Kerala. First PMRU was established in Kerala on 03.01.2019.

b. First instalment of 90% of non-recurring grant was released to the States of Kerala (₹4.50 lakh), Odhisha (₹6.30 lakh) and Gujarat (₹6.30 lakh) during the year 2016-17. There is a pending Parliament Assurance given for Lok Sabha Unstarred Q. No. 2544, dated 02.08.2016 in which the status of establishing PMRUs in the seven pilot States are to be submitted. These States are Kerala, Gujarat, Odisha, Maharashtra, Haryana, Manipur and Assam. So far PMRU has been registered as a Society in the State of Kerala. It is imperative to register PMRUs in these states without further delay.

c. NPPA conducted a National Workshop in this regard on 10th January, 2019 at New Delhi to discuss the operational issues. Further, Memorandum of Association of PMRU as a society constituted in Kerala has been shared vide DO Letter No. A-16011/ 2016-Div III/ M&E/ NPPA dated 14.01.2019 with States concerned as an option for society registration.

Member-Secretary, NPPA requested the other State drugs controllers to take quick initiation to establish PMRUs in their States.

(ii) Submission of references regarding price compliance

DCC was apprised that, monitoring of price compliance and availability of drugs is done on the basis of purchase of samples, complaints received and the most important and effective way among these is references received from Drugs Controllers.

Member-Secretary, NPPA informed that all offices of State Drugs Controllers may collect the samples of scheduled formulation for checking of price compliance by pharma companies in their respective jurisdiction and also stated that till date references are received from the offices of only 12 Drug Controllers. Hence, she requested other State Drugs Controllers to collect samples and provide references

along with supporting documents such as invoices related to purchase of medicine or price declaration of retailers and samples/ photo copy of samples for effective monitoring of price compliance.

(iii) SDCs to pursue where companies have not submitted requisite data even after issue of show cause notice

Member-Secretary, NPPA apprised the DCC that, some of the manufacturers does not furnish production and sales data of the subject formulation even after issue of show cause notice without quantity and the matter is referred to SDCs with a copy to the Principal Secretary/ Secretary (Health) in the State where the manufacturers' headquarter is situated with a request for pressing upon them to furnish required information within a further period of 30 days and also to verify their credentials through inspection of their offices and factory premises if required.

She also stated that, in many cases, it has been noticed that even after reminders, the manufacturer/ marketing companies are not submitting the requisite data and requested once again all State Drugs Controllers for pushing the manufacturers to furnish required information to NPPA.

DCC deliberated and took note of the above issues for taking proactive action in this regard.

ADDITIONAL AGENDA NO. S3

CONSIDERATION OF THE PROPOSAL TO AMEND SCHEDULE V (QUALITY MANAGEMENT SYSTEM FOR MEDICAL DEVICES AND *IN-VITRO* DIAGNOSTIC MEDICAL DEVICES) OF MEDICAL DEVICE RULES, 2017 IN LINE WITH ISO 13485: 2016

DCC was apprised that Schedule V of Medical Device Rules, 2017 deals with Quality Management System for Medical Devices and *in-vitro* diagnostic medical devices and it is largely based on requirements of ISO 13485:2003. These provisions have been updated by ISO in its third edition which will be effective from 01.03.2019.

This office has received a letter from DG, BIS through Ministry stating that "As the standards are dynamic and are revised periodically, it is submitted that in the Medical Devices Rules, 2017; instead of reproducing the requirements of IS/ISO 13485, a reference to the Indian Standard, i.e., IS/ISO 13485 may be made, which will take care of any revision of the standard in future without resorting to amending the rules".

DCC after deliberation felt that instead of making reference to the IS/ISO 13485, it is appropriate to prepare the necessary guidelines and requirements in Indian context considering the IS/ISO 13485 guidelines.

ADDITIONAL AGENDA NO. S4

CONSIDERATION OF THE PROPOSAL FOR PROCUREMENT OF AUTHENTICATED INDIAN PHARMACOPOEIA - 2018 BY THE PHARMACEUTICAL MANUFACTURERS, LABORATORIES, IMPORTERS, EXPORTERS AND OTHER STAKEHOLDERS

Representative from IPC requested DCC to sensitize the Pharmaceutical Manufacturers, Laboratories, Importers, Exporters and other Stakeholders under their jurisdiction, to procure authenticated copy of IP-2018 in order to ensure better compliance of standards and overall improvement of quality of drugs in the country.

DCC recommended that all State Drug Controllers should take measures to insist the stakeholders to procure the authenticated copy of IP-2018.

ADDITIONAL AGENDA NO. S5

CONSIDERATION OF PROPOSAL FOR SETTING UP OF PUBLIC RELATION OFFICES IN ALL STATES AND CDSCO ZONAL AND SUB-ZONAL OFFICES FOR STRENGTHENING OF INNOVATION AND EASE OF DOING BUSINESS

DCC was apprised that DCG(I) convened an interactive meeting with the officers/ staff of CDSCO(HQ) on 01.01.2019 and discussed various issues with a view to improving enforcement and general perception about regulatory system in India with regard to its efforts to protect and promote the public health by ensuring the quality, safety and efficacy of drugs available in the country. During the meeting it was discussed that for the status on follow up of creation of Public Relation Offices (PRO) at State Level by SLAs.

DCC members appreciated the initiation of CDSCO and recommended to set up PROs in their respective organizations, headed by a senior officer to guide, assist and handhold investors in various phases of manufacture of drugs in the country.

ADDITIONAL AGENDA NO. S6

CONSIDERATION OF PROPOSAL TO SHARE TECHNICAL DOSSIERS/ INSPECTION REPORTS/ RECALLS ETC. WITH STATE LICENSING AUTHORITIES AND ZONAL OFFICE OF CDSCO THROUGH WEB BASED MECHANISM

DCC felt that the matter needs to be deliberated in detail and deliberated to take up the agenda in next DCC meeting.

ADDITIONAL AGENDA NO. S7

CONSIDERATION OF PROPOSAL FOR CONTROL ON MISUSE/ DIVERSION OF SCHEDULED DRUGS

State Drugs Controller, Haryana requested Shri. Rajesh Nandan Srivashtav, Deputy Director General, Operations from Narcotic Control Bureau to clarify 2001 and 2009 Notification on whole quantity to be taken in to consideration for the purpose of legal adjudication especially in light of S.O.826(E) dated 14.11.1985. As per S.O.826(E), exemption of strength is given when a Narcotic and Psychotropic substance is covered under Schedule H, H1 or X of the Drugs and Cosmetics Act, then these should not attract rigours of punishment of NDPS Act if having umbrella of protection of Drugs Act

Shri. Rajesh Nandan Srivashtav, Deputy Director General, Operations from NCB clarified that if person is complying with provisions of drugs Act then rigours of NDPS are not attracted. He also informed that 2009 notification is under scrutiny of Hon'ble Supreme Court therefore he is not commenting on interpretation of whole quantity in 2009 notification.

He assured that if person is complying with provisions of Drugs and Cosmetics Act then rigours of NDPS Act and Rules are not attracted this will be communicated to officers of CNB in Zonal Offices.

On request of SDC Haryana he assured that a communication will be sent to commissioner CNB Gwalior that quota of Narcotic or Psychotropic substance may be issued to licensed Drug manufacturer after considering credibility with justification and a copy of quota allocation may also be endorsed to concern State Drugs Controller for its consumption verification.

The meeting ended with the vote of thanks to the Chair.

NOTE: ANNEXURE-A: List of Participants

****

ANNEXURE-A

List of the participants of 55th Drugs Consultative Committee meeting held on 31.01.2019 & 01.02.2019 at New Delhi under the Chairmanship of Dr. S. Eswara Reddy, Drugs Controller General (India)

A. STATE/UTs DRUGS CONTROL ORGANIZATIONS

S. NO.	STATE	NAME	DESIGNATION
1.	Andhra Pradesh	Shri. K.V. Rajendranath Reddy	Director General, DCA
2.	Arunachal Pradesh	Not represented	
3.	Assam	Shri. Ashim Kumar Nath	Joint Drugs Controller
4.	Bihar	Shri. Ravindra Kumar Sinha	State Drugs Controller
5.	Chhattisgarh	Not represented	
6.	Goa	Smt. Jyoti J. Sardesai	Director, FDA
7.	Gujarat	Dr. H.G. Koshia	Commissioner, FDCA
8.	Haryana	Shri. N.K. Ahooja	State Drugs Controller
9.	Himachal Pradesh	Shri. Navneet Marwaha	State Drugs Controller
10.	Jammu and Kashmir	Smt. Lotika Khajuria	Controller, Drugs & Food
11.	Jharkhand	Smt. Ritu Sahay	Director (Drugs)
12.	Karnataka	Shri. Amaresh Tumbagi	State Drugs Controller (A/C)
13.	Kerala	Not represented	
14.	Madhya Pradesh	Shri. Shobhit	Dy. Drugs Controller, FDA
15.	Maharashtra	Shri. Amrut Nikhade	Jt. Commissioner (HQ), FDA
16.	Manipur	Not represented	
17.	Meghalaya	Shri. Antony Laloo	Sr. Drugs Inspector
18.	Mizoram	Shri. Lal Sawma Pachuau	Joint Director, FDA
19.	Nagaland	Not represented	
20.	Odisha	Smt. Mamina Patnaik	State Drugs Controller (I/C)
21.	Punjab	Shri. Pradeep Kumar	Jt. Commissioner, FDA
22.	Rajasthan	Shri. Raja Ram Sharma	State Drugs Controller
23.	Sikkim	Not represented	
24.	Tamil Nadu	Shri. K. Sivabalan	Director of Drugs Control
25.	Telangana	Dr. B. Venkateswarlu	Joint Director, DCA
26.	Tripura	Dr. N. Goswami	Dy. Drugs Controller
27.	Uttar Pradesh	Shri. Dinesh Kumar Tiwari	Assistant Commissioner (Drug)
28.	Uttarakhand	Shri. Tajber Singh	State Drugs Controller
29.	West Bengal	Shri. Swapan Kumar Mondal	Director of drugs control (Acting)
30.	Andaman and Nicobar	Not represented	
31.	Chandigarh	Shri. Amit Duggal	Sr. Drug Control Officer

S. NO.	STATE	NAME	DESIGNATION
32.	Dadar and Nagar Haveli	Not represented	
33.	Daman and Diu	Not represented	
34.	Delhi	Shri. Atul Kumar Nasa	DDC & Controlling Authority
		Shri. K R Chawla	Asst. Drugs Controller
35.	Lakshadweep	Not represented	
36.	Pondicherry	V. Karthikeyan	State Licensing Authority

B. INVITEES

S. No.	NAME	DESIGNATION
1.	Ms. Preeti Sudan	Secretary, MoHFW
2.	Shri. Arun Singhal	Additional Secretary, MoHFW
3.	Dr. Mandeep Kumar Bhandari	Joint Secretary, MoHFW
4.	Ms. Rita Teaotia	Chairperson, FSSAI
5.	Shri. R.N. Shrivastava	Dy. Director General, Narcotics Control Bureau
6.	Dr. Muzamil Rehman	Assistant Adviser (U), Ministry of AYUSH
7.	Dr. Rachna Paliwal	Research Officer(H), Ministry of AYUSH
8.	Smt. Ritu Dhillon	Member Secretary, NPPA
9.	Shri. Rajesh K. Aggarwal	Director M&E / Administration, NPPA
10.	Shri. AlokRanjan	Assistant Director, NPPA
11.	Dr. V. Kalaiselvan	Principal Scientific Officer, IPC
12.	Shri. Chandan Kumar	Finance & Accounts Officer, IPC
13.	Shri. Rishi Prakash	Joint Director, CDAC
14.	Ms. PayalSaluja	Principal Technical Officer, CDAC
15.	Ms Shruti Gupta	Project Engineer, CDAC
16.	Shri. Rahul Kumar Gautam	Project Engineer, CDAC
17.	Shri. NawalKishor	Project Associate, CDAC

C. DRUG TESTING LABORATORIES

S.No.	LABORATORY	NAME	DESIGNATION
1.	CDL Kolkata	Shri. C Hariharan	Director/In-Charge
2.	CDL, Kasauli	Dr. Arun Bhardwaj	Director
3.	CDTL, Mumbai	Dr. Raman Mohan Singh	Director
4.	CDTL, Chennai	Dr. N. Murugesan	Director
5.	CDTL, Hyderabad		
6.	RDTL, Chandigarh	Dr. R. A. Singh	Director
7.	RDTL, Guwahati	Not represented	

D. ZONAL/ SUB ZONAL OFFICES OF CDSCO

S. No.	OFFICES	NAME	DESIGNATION
ZONE			
1.	North Zone, Ghaziabad	Shri. AseemSahu	Deputy Drugs Controller (India)
		Dr. Ajay Sachan	Asst. Drugs Controller (India)
2.	East Zone, Kolkata	Shri. A.K. Chatterjee	Asst. Drugs Controller (India)
3.	West Zone, Mumbai	Shri. P.B.N. Prasad	Deputy Drugs Controller (India)
		Smt. Rubina Bose	Deputy Drugs Controller (India)
4.	South Zone, Chennai	Smt. Shanthy Gunashekharan	Deputy Drugs Controller (India)
		Dr. S. Manivannan	Deputy Drugs Controller (India)
5.	Hyderabad Zone	Smt. A.Visala	Deputy Drugs Controller (India)
6.	Ahmedabad Zone	Shri. Arvind Kukrety	Deputy Drugs Controller (India)
SUB ZONE			
1.	Baddi Sub-zone	Shri. B.K. Samantray	Deputy Drugs Controller (India)
2.	Bangalore Sub-zone	Shri. B. Kumar	Deputy Drugs Controller (India)
3.	Guwahati Sub-zone	Shri. A. Senkathir	Deputy Drugs Controller (India)
4.	Indore Sub-zone	Shri. Sunil M Joshi	Asst. Drugs Controller (India)
5.	Varanasi Sub-zone	Shri. Vinay Kumar Gupta	Asst. Drugs Controller (India)
6.	Jammu Sub-zone	Not represented	
7.	Goa Sub-zone	Not represented	

E. CDSCO HEAD QUARTER

S. No.	NAME	DESIGNATION
1.	Dr. S. Eswara Reddy	Drugs Controller General of India
2.	Dr. V. G. Somani	Joint Drugs Controller (India)
3.	Dr. K Bangarurajan	Joint Drugs Controller (India)
4.	Shri A. C. S. Rao	Deputy Drugs Controller (India)
5.	Shri. A.K. Pradhan	Deputy Drugs Controller (India)
6.	Dr. S. Manivannan	Deputy Drugs Controller (India)
7.	Shri. R. Chandrashekhar	Deputy Drugs Controller (India)
8.	Shri. Sanjeev Kumar	Deputy Drugs Controller (India)
9.	Ms. Swati Srivastava	Deputy Drugs Controller (India)
10.	Shri. GulashanTaneja	Deputy Drugs Controller (India)
11.	Dr. Naresh Sharma	Deputy Drugs Controller (India)
12.	Shri. Jayant Kumar	Deputy Drugs Controller (India)
13.	Dr. Ravikant Sharma	Deputy Drugs Controller (India)

S. No.	NAME	DESIGNATION
14.	Shri. Gaurav Kumar	Asst. Drugs Controller (India)
15.	Dr. Santosh Indraksha	Asst. Drugs Controller (India)
16.	Shri. Dhananjay Keshavrao Sable	Asst. Drugs Controller (India)
17.	Shri. Vijay Vitthalrao Chandrakar	Asst. Drugs Controller (India)
18.	Shri. Srinivasan Kaliyappan Munisamy	Asst. Drugs Controller (India)
19.	Shri. Meshram Pramod Annan Rao	Asst. Drugs Controller (India)
20.	Shri. SomnathBasu	Asst. Drugs Controller (India)
21.	Shri. Inderjeet Singh Hura	Asst. Drugs Controller (India)
22.	Shri. Jayant Gangakhedkar	Asst. Drugs Controller (India)
23.	Shri. Rahul S. Shakhapure	Asst. Drugs Controller (India)
24.	Shri. Ankit Sharma	Asst. Drugs Controller (India)
25.	Shri. K.Narendran	Asst. Drugs Controller (India)
26.	Shri. Kishore Kumar Dondilkar	Asst. Drugs Controller (India)
27.	Smt. P. Indira	Asst. Drugs Controller (India)
28.	Shri. Y K Shelar	Asst. Drugs Controller (India)
29.	Shri. PramodMadhukarPatil	Asst. Drugs Controller (India)
30.	Shri. Sella SenthilMarimuthu	Asst. Drugs Controller (India)
31.	Shri. Sushanta Sarkar	Asst. Drugs Controller (India)
32.	Shri. Arvind RampratapHiwale	Asst. Drugs Controller (India)
33.	Shri. Sidharth Sahai Malhotra	Asst. Drugs Controller (India)
34.	Shri. Ashish Rai	Drugs Inspector
35.	Shri.Shivadev D	Drugs Inspector
36.	Shri.Gunda Raghuvaran	Drugs Inspector
37.	Shri. RajeshamPambala	Drugs Inspector
38.	Shri Ashish Kaundal	Drugs Inspector
39.	Shri. Milind P. Patil	Drugs Inspector
40.	Shri.John Gerard	Drugs Inspector
41.	Shri. Vinod Kumar Gupta	Drugs Inspector
42.	Shri. Dhinesh Pandian	Drugs Inspector
43.	Shri. Rajesh Kumar Verma	Drugs Inspector
44.	Shri. Sandeep Kumar	Drugs Inspector
45.	Shri. Arunachalam C.	Drugs Inspector
46.	Shri. Fahim Khan	Drugs Inspector
47.	Shri. Munish Kakkar	Drugs Inspector
48.	Shri. Mukesh Kumar	Drugs Inspector
49.	Shri. Jayasenthil N.K.	Drugs Inspector

S. No.	NAME	DESIGNATION
50.	Shri. C Manivillavan	Drugs Inspector
51.	Shri. S.P.N.Singh	Drugs Inspector
52.	Shri. Pramod Kumar	Drugs Inspector
53.	Ms. Neha Sharma	Drugs Inspector
54.	Shri. Sandeep Chaudary	Drugs Inspector
55.	Shri. Srinivasan	Drugs Inspector
56.	Shri. Devashish	Drugs Inspector
57.	Shri. Dev Kumar	Drugs Inspector
58.	Shri. Manish	Drugs Inspector
59.	Shri. Deepak Dagar	Drugs Inspector
60.	Shri. Mangal Jyoti Das	Asst. Drugs Inspector