REPORT OF 51ST MEETING OF DRUGS CONSULTATIVE COMMITTEE HELD ON 09TH JUNE, 2017 AT NEW DELHI

Inaugural Deliberations

(LIST OF PARTICIPANTS IS AT ANNEXURE I)

Dr. G. N. Singh, Drugs Controller General (India) and Chairman, Drugs Consultative Committee, welcomed the participants. He briefed the members about various initiatives taken by CDSCO and Ministry in the recent past to streamline the drug regulatory system in the country. He stated that various amendments in the D&C Rules relating to regulation of import of drugs, clinical trial have been made. Recently a separate set of rules for regulating Medical devices - Medical Device Rules, 2017 have been notified.

He further mentioned that capacity building project which was slow in the previous 2-3 years has now gained momentum. Central govt. has already disbursed about 81 crores to various States under Centrally Sponsored Scheme for strengthening of drug regulatory system in the States.

While citing the challenges being faced for uniform implementation of the provisions of D&C Act, 1940 and Rules, 1945 he stressed that there should be uniform organizational structure with technical cadre driven regulatory officials with flexible promotional avenues at the centre and in the states, on the similar lines as exists in CSIR, DRDO, ICMR and other scientific institutions.

As regards patient safety he informed that Pharmacovigillance Programme of India (PvPI) is actively involved in ADR monitoring of marketed drugs through 250 ADR monitoring centers across the country. PvPI with IPC as National Co-ordination centre is going to be declared soon by WHO as WHO collaborating centre for regulatory Pharmacovigillance.

He appreciated the members for their support provided to CDSCO for NRA assessment by WHO held in February 2017, in which the vac-

cine regulatory system in the country has been declared as functional with maturity level of 4, the maximum level as per WHO, in 5 out of 9 functions.

I

Thereafter, the DCG(I) requested all the members to express their views on various issues for strengthening of the regulatory system in the country. Accordingly, issues deliberated and recommendations made by the committee are as under:

1) Cadre restructuring in State Drugs Controls for uniform implementation of provisions of the Drugs and Cosmetics Act, 1940 and Rules, 1945
   - The post of Drugs Inspector should be re-designated as Drugs Control Officer.
   - The grade pay of Assistant Drugs Inspector should be raised to Rs.4800 in Pay Band-2.
   - The grade pay of Drugs Inspector should be raised to Rs.5400 in Pay Band-2.
   - All the other higher posts should accordingly re-organized.
2) The Central Govt. should issue direction to the State Governments to ensure adequate regulatory officials which will be commensurate with the number of sale outlets and manufacturing units located in the respective States considering that there should be one official for every 200 sale outlets and one official for every 50 manufacturing units.
3) There should be provisions for deputation of State regulatory officials to the Central regulatory system and vice versa.
4) The minimum experience for Licensing Authorities (LA) relating to manufacturing and sale of drugs should be raised adequately.
5) The practice of having multiple LA in a State for regulation of manufacture of drugs may be replaced by a single LA with provision for delegation of powers to other regulatory officials.
6) Guidelines, directions as and when issued, should be communicated to the State Government and not to the State Drugs Controllers for

ensuring effective uniform implementations of such guidelines directions.

7) It was suggested that Drugs Control Authority of each State should create an Intelligence cell with a Nodal Officer for market surveillance and conducting investigation in respect of Spurious, adulterated drugs in co-ordination with CDSCO.
8) Drugs samples from supply chain of procurement agencies needs focused monitoring for ensuring quality of the drugs.
9) The procurement agencies get their sample tested at approved private drug testing laboratories and obtain test reports in Form 39, which is supposed to be issued by such laboratories only to drug manufacturers who do not have testing facilities. The Drugs and Cosmetics Rules, 1945 should be amended to prescribe a separate Form for issuing test reports by such laboratories for procurement agencies.
10) The committee while appreciating the recently conducted National Drugs Survey, mentioned that a system should be put in place to address the issues, if any, relating to the Survey, when brought to the notice of the authority.
11) Guidelines should be prepared for disposal of expired drugs- a committee comprising Drugs Controllers of Telangana, MP and DDC (I), Hyderabad zone should be constituted in this regard.
12) Weak areas of market identified on the basis of risk analysis and intelligence information shall be kept under active quality surveillance of GAP by conducting special operations.
13) Regulatory officials should not participate in the procurement activities as there may be conflict of interest.
14) Minutes of all DCC and DTAB meetings held so far should be compiled and uploaded in CDSCO website.

II

Shri K. L. Sharma, who joined the meeting post lunch session, thanked the Committee for having invited him for this meeting. He shared various initiatives taken by the Ministry for streamlining and strengthening the regulatory system in the country. Details are as under:

- For strengthening of drug regulatory system in the States, so far, the Central Govt. has disbursed about 81 crores to various States like AP, Gujarat, HP, Karnataka, Jharkhand, etc. As and when sanction for more money is received, the same will be disbursed to other states.
- Initiatives should be taken to upgrade the regulatory system including GMP so that we can apply in next about two years for PIC/S membership.
- Both Centre and State regulatory systems should work together with a feeling of oneness for effective and uniform implementation of the provisions of the Act and Rules.
- The State and UT Drugs Controllers should participate the next Good Regulatory Practices workshop to be held on August 2017 in Bhopal, MP.
- We are going to rewrite whole set of Rules separately for new drugs and clinical trials, manufacture for sale, sale of drugs including sale on internet, rules for cosmetics regulation etc.
- Recruitment rules for various posts at CDSCO have been uploaded in the website. There are some provisions in the proposed rules for deputation at the level of JDC(I) and DDC(I).
- 10% NSQ of the samples drawn from govt. sources observed in the National Survey is not acceptable. We should have effective measures to address this challenge.
- Finally, measures/ initiatives should be taken to transform the Indian regulatory system into a robust regulatory system to be considered on par at Global level.

III

Thereafter, the 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 50TH DCC MEETING HELD ON 4TH & 5TH NOVEMBER 2016 AND ACTION TAKEN IN THE MATTERS ARISING OUT OF THE MEETING

- The report of the 50th meeting of the DCC was considered approved as there were no comments from the members.

- For creation of online database under SUGAM portal, the respective State Drugs Control may approach the CDAC for any queries/ clarifications in the matter.

- In view of constraints of manpower in the States, the other Department/ Organization like FSSAI, Dept. of Pharmaceuticals, Dept. dealing with Cigarettes and Other Tobacco Products Act, 2003 (COTPA) etc. who have issued various notifications involving State Drugs Inspectors (DI) in additional activities like Food regulation, pricing etc. should be requested to reconsider the matter, so that the DIs can focus only in regulatory activities covered under the provisions of the D & C Act, 1940 and Rules, 1945.

- In light of the recent amendment in the Rules specifying a time limit of 60 days for Govt. Analyst for issuing the test report, as and when samples are sent to the Govt. Analyst by the Drugs Inspectors, the respective LA should take measures to ensure timely availability of the specification, method of analysis and reference standards etc. required for testing. The conditions of manufacturing licence under the Drugs and Cosmetics Rules should also be amended under Rule-76 and Rule-78 for manufacture of placebo as required for testing of a drug manufactured under the licence.

- As regards recalling of sub-standard drugs by manufacturer, based on test report of Govt. Analyst, the committee recommended that the manufacturer should recall such drug promptly even if the manufacturer intends to challenge the report of the Govt. Analyst under the provision of the Act.

- SOP prepared for handling of NSQ samples by the Director, RDTL, Chandigarh and Director, CDTL, Chennai should be uploaded in the CDSCO website seeking public comments within 30 days.

- All State Drugs Controllers should ensure that all the manufacturing/ quality control units located in their respective jurisdiction has original copy of latest edition of IP and such units should procure and use the available IP reference standards for maintaining quality of the drugs manufactured/ tested by them.

- All the State Drugs Control Authorities should take measures to establish quality management system encompassing (i) quality policy (ii) quality manual (iii) organogram (iv) job responsibilities (v) SOPs of processes undertaken (vi) guidelines and format for all the regulatory activities undertaken (conduct of inspection, issuance of licence of manufacturing and sale premise, etc.), training of concerned for the job, mechanism to obtain customer feedback and to attend it (customer means any department, person, public dealing with and expecting services from the state drug authorities), internal audits of processes and timelines for all processes, key performance indicators like percentage of work done and time taken for the same in comparison to established timeline, management responsibilities to review performance, internal audits and customer complaints/feedback.

  The main aim of quality management system is to bring transparency, accountability and systematic approach through publishing all data of licenses issued, names of licensed manufacturers and products, details of regulatory action taken, not of standard quality drugs and action taken, recalls, etc. with continued review and continued improvement in the work done by concerned regulatory agencies with respect to their core objectives.

  All state drug control authorities should ensure that GMP inspections are planned, conducted and reported as per the SOPs published in the CDSCO website and by trained inspectors with adequate knowledge and experience with special emphasis on vaccines and other sterile products.

  All the state drug authorities should direct Drugs Inspectors under their control who are responsible for inspection of wholesale and retail premises, to include specific points on procurement, storage and distribution of vaccines, whenever they are inspecting such premises.

  Further the state drug authorities are required to conduct post marketing surveillance through regular sampling and should ensure that 'Guidelines on

recall and rapid alert system for drugs' and 'Guidelines on Good Distribution Practices for biological Products' are implemented by manufacturers and all concerned.

AGENDA NO.2

AN UPDATE ON THE CENTRAL SCHEME FOR STRENGTHENING OF THE STATES DRUGS DEPARTMENTS UNDER 12TH FIVE YEAR PLAN

- Measures should be taken to disburse the funds to the States other than those who have already received the fund at the earliest.

AGENDA NO.3

AN UPDATE ON MEDICAL DEVICES RULES, 2017

- DCC noted various provisions under the Rules and recommended that the Medical Device officers to be appointed under the Rules should have B. Pharm./ M. Pharm. Such officer should undergo training in Medical Device Regulation under a training module being developed under joint collaboration between Delhi Pharmaceutical Science and Research University and IPC, Ghaziabad or any other institutions which deems fit for such activity.

AGENDA NO.4

AN UPDATE ON RISK BASED INSPECTION EVALUATION OF MANUFACTURING FACILITIES FOR ENSURING QUALITY OF MEDICINES BY MONITORING OF GMP COMPLIANCE

- The State Drugs Controllers should take appropriate action on the reports of Risk Based inspection and update the action taken to CDSCO.

AGENDA NO.5

AN UPDATE ON THE ISSUE OF MISUSE OF OXYTOCIN BY DAIRY OWNERS TO EXTRACT MILK FROM MILCH ANIMALS

- State Drugs Controllers should take similar actions as taken by CDSCO by issuing Public Notice for receiving complaints regarding illegal production of Oxytocin, strict monitoring of manufacturing units of Oxytocin through inspection and regulatory action, where ever necessary, giving wide publicity to educate the public about the ill effect of illegal use of Oxytocin. Some of the states like Bihar where the licence for Oxytocin (Vet) manufacturing are given years back requires to be re-visit for their regulatory compliance.

AGENDA NO.6

CONSIDERATION FOR REGULATION OF PATHOLOGY AND CLINICAL DIAGNOSTIC LABORATORIES IN INDIA

- Members may give their valuable suggestion for discussion in the next DCC meeting

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

ANNEXURE I

List of the participants of 51st Drugs Consultative Committee meeting held on 09thJune 2017 at New Delhi under the Chairmanship of Dr. G. N. Singh, Drugs Controller General (India)

A. STATE DRUGS CONTROL ORGANIZATIONS

S. No.	NAME AND ADDRESS OF THE PARTICIPANTS
1.	Dr. Ravi Shankar, Director General, Drugs and Copyrights, Andhra Pradesh, Vengalrao Nagar, Hyderabad – 500 038
2.	Shri M.Amruth Rao, Jt. Director & Licensing Authority, Telangana, Drugs Control Bhawan, Vengalrao Nagar, Hyderabad – 500 038
3.	Shri Atul Kumar Nasa, Assistant Drugs Controller, Delhi, F-17, Karkardooma, Delhi 110 032
4.	Shri M.P.Gupta, Drugs Controller, Govt. of Haryana, Govt. Dispensary, Sector – 20, Panchkula, Haryana – 139 109
5.	Shri Navneet Marwaha, Drugs Controller, Himachal Pradesh Sai Road Baddi, Disstt. Solan-173205
6.	Shri. Surinder mohan ACD(HB), Patoli Mangotrian, Jammu & Kashmir
7.	Shri Amaresh Tumbagi, Deputy Drugs controller(HQ), Karnataka, Palae Road, Bangalore, Karnataka– 560 001
8.	Shri Salim A, Veljee, Director, Food & Drugs Admin.-Goa, Old IPHB Complex, Altinho, Panaji, Goa-403001
9.	Shri Ravi. S. Menon, Drugs Controller (I/c), Red Cross Road, Thiruvananthapuram, Kerala
10.	Shri Shobhit Dy.DC, FDA, Idgah Hills, Bhopal, Madhya Pradesh.
11.	Shri Omprakash S. Sadhwani, Joint Commissioner (HQ), FDA, Opposite RBI, Bandra Kurla Complex, Bandra East, Mumbai, Maharashtra,
12.	Shri Lal Sawma, Joint Director, FDA, Department Of Health Services, Dinthar Veng, Aizwol, Mizoram
13.	Shri H. Mahapatra, Drugs Controller, Dte of Drugs Control, Nandankanan Road, Bhuvneswara, Odisha,
14.	Shri Amit Duggal, Sr.DCO, Directorate of Health & Family Welfare, Pariwar Kalyan Bhawan, Sector – 34A, Chandigarh
15.	Shri S. Abdul Khader, Director Drugs Control (I/c), Tamil Nadu
16.	Dr. Neeraj Kumar, Drugs Inspector, Uttrakhand, Dte. of Medical Health, Sahashtra Dhara Road, Dehradun

S. No.	NAME AND ADDRESS OF THE PARTICIPANTS
17.	Shri Himanshu kumar, Pr.Secy, FS &DA, UP
18.	Smt Ritu Sahay, Director Drugs, Jharkhand
19.	Shri. Ajay Phetan, Dte. of medical health Services, Jaipur, Rajasthan
20.	Shri Ravindra Kumar Singh, State Drugs Controller, Bihar
21.	Shri Hemant shrivastava, H.O.D Building Block-A, 4th floor, Indravati bhawan , naya Raipur, Chattisgarh
22.	Shri Pardeep kumar, Joint Commissioner, Punjab.
23.	Dr.M.G.Koshia, Commissioner, FDCA, Gujarat

B. INVITEE

S. No.	NAME AND ADDRESS OF THE PARTICIPANTS
24.	Shri K.L.Sharma, Joint Secretary, Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi.

C. DRUG TESTING LABORATORIES

S. No.	NAME AND ADDRESS OF THE PARTICIPANTS
25.	Shri. C Hariharan,, Director/In-Charge,Central Drugs Laboratory, 3, Kyd Street, Kolkata 700016
26.	Dr. Parthajyoti Gogoi, Director-in-Charge Regional Drugs Testing Laboratory, Guwahati-781 037 (Assam)
27.	Dr. Raman Mohan Singh, Director, Central Drugs Testing Laboratory, Zonal FDA Bhawan, Belasis Rd, Mumbai-400008
28.	Dr. R. A. Singh, Director, Regional Drug Testing Laboratory, Sector 39-C, Chandigarh-160036
29.	Dr. N. Murugesan, Director,Central Drug Testing Laboratory, Chennai

D. ZONAL/ SUB ZONAL OFFICES OF CDSCO

S. No.	NAME AND ADDRESS OF THE PARTICIPANTS
30.	Shri A. K. Pradhan, DDC(I), North Zone
31.	S. Mukhopadhyay, DDC(I), East Zone
32.	Shri P.B.N. Prasad, DDC (I), Hyderabad Zone
33.	Smt Shanti Gunashekharan, DDC (I), Bangalore Sub-Zone
34.	Dr. Ajay Sachan, ADC(I) I/C, North Zone

E. CDSCO HEAD QUARTERS

S. No.	NAME AND ADDRESS OF THE PARTICIPANTS
35.	Dr. G. N. Singh, Drugs Controller General (India), CDSCO, FDA Bhawan, New Delhi
36.	Dr. S. Eswara Reddy, JDC(I), CDSCO, FDA Bhawan, New Delhi
37.	Dr. V. G. Somani, JDC(I), CDSCO, FDA Bhawan, New Delhi
38.	Shri A. Chandrashekar Rao, DDC(I), CDSCO, FDA Bhawan, New Delhi
39.	Shri A. Ramkishan, DDC(I), CDSCO, FDA Bhawan, New Delhi
40.	Shri Aseem Sahu, DDC(I) , CDSCO, FDA Bhawan, New Delhi
41.	Smt. Rubina Bose, DDC(I), CDSCO, FDA Bhawan, New Delhi
42.	Smt. Swati Srivastava, DDC(I), CDSCO, FDA Bhawan, New Delhi
43.	Shri Rajesham Pambala, DI, CDSCO, FDA Bhawan, New Delhi
44.	Ms. Gunja Chaturvedi, ADI, CDSCO, FDA Bhawan, New Delhi